The formulations of the following products containing vitamins have been revised as per Schedule V of the Drugs and Cosmetics Rules.

1. Basiton Forte Tablets
2. Phosfomin
3. Phosfomin Iron
4. Rubraplex Elixir
5. Rubraton Elixir
6. Rubraton Pediatric Elixir
7. Theragran Tablets
8. Theragran Pediatric Drops
9. Theragran Syrup
10. Theragran-GR Tablets
11. Theragran-M Tablets
12. Vimgran Tablets

For the revised formulations please refer to the supplement provided along with this Product Reference Book.

SARABHAI CHEMICALS

SUPPLEMENT
TO

PRODUCT REFERENCE BOOK

1983

BASITON ® FORTE — **Tablets**

Vitamin B Complex with Vitamin C Tablets
(FOR THERAPEUTIC USE)

Each tablet contains

Thiamine Mononitrate (B_1)	10 mg
Riboflavine (B_2)	10 mg
Pyridoxine Hydrochloride (B_6)	3 mg
Niacinamide	100 mg
Calcium Pantothenate	50 mg
Cyanocobalamin (B_{12})	15 mcg
Vitamin C (as Sodium Ascorbate)	150 mg
Folic Acid	1 5 mg

(Extra Vitamins added to compensate for loss on storage)

Dosage One tablet daily or as directed by the physician

PHOSFOMIN ‡ — **Elixir**

Multiple Glycerophosphates B Complex Elixir
(FOR PROPHYLACTIC USE)

Each 15 ml contains

Calcium Gylcerophosphate	0 11 g
Sodium Glycerophosphate	80 mg
Potassium Glycerophosphate	20 mg
Manganese Glycerophosphate	10 mg
Thiamine Mononitrate (B_1)	1 mg
Riboflavine (B_2)	1 mg
Pyridoxine Hydrochloride (B_6)	0 75 mg
Niacinamide	13 mg
d Panthenol	2 5 mg
Cyanocobalamin (B_{12})	0 5 mcg
Alcohol	1 75 ml

In a pleasantly flavoured syrup base
Alcohol 11% v/v

(Extra Vitamins added to compensate for loss on storage)

Dosage One tablespoonful two times daily or as directed by the physician

PHOSFOMIN ‡ IRON — **Elixir**

Multiple Gylcerophosphates B Complex with Iron Elixir
(FOR PROPHYLACTIC USE)

Each 15 ml contains

Calcium Glycerophosphate	0 11 g
Sodium Glycerophosphate	80 mg
Potassium Glycerophosphate	20 mg
Manganese Glycerophosphate	10 mg
Iron & Ammonium Citrate	46 5 mg
Thiamine Mononitrate (B_1)	1 mg
Riboflavine (B_2)	1 mg
Pyridoxine Hydrochloride (B_6)	0 75 mg
Niacinamide	13 mg
d Panthenol	2 5 mg
Cyanocobalamin (B_{12})	0 5 mcg
Alcohol	1 75 ml

In a pleasantly flavoured syrup base
Alcohol 11% v/v

(Extra Vitamins added to compensate for loss on storage)

Dosage One tablespoonful two times daily or as directed by the physician

RUBRAPLEX® **Elixir**

Iron B Complex and B_{12} Vitamins Elixir
(FOR THERAPEUTIC USE)

Each 15 ml (approximately 1 tablespoonful) contains

Iron Elemental (as Ferric Ammonium Citrate 394 5 mg and Ferric Chloride Hydrated 144 mg)	114 mg
Thiamine Mononitrate (B_1)	4 5 mg
Vitamin B_2 (as Riboflavine 5 Phosphate Sodium)	4 5 mg
Niacinamide	48 mg
Cyanocobalamin (B_{12})	7 5 mcg
Pyridoxine Hydrochloride (B_6)	1 5 mg
d Panthenol	24 mg
Alcohol	1 8 ml

Alcohol 12% v/v

(Extra Vitamins added to compensate for loss on storage)

Dosage One tablespoonful two times daily or as directed by the physician

RUBRATON® ELIXIR **Elixir**

Vitamin B_{12} with Folic Acid and Iron Elixir
(FOR THERAPEUTIC USE)

Each 15 ml (approximately 1 tablespoonful) contains

Cyanocobalamin	7 5 mcg
Folic Acid	0 75 mg
Ferric Ammonium Citrate (providing Iron 114 mg)	0 531 g
Alcohol	1 8 ml

Alcohol 12% v/v

(Extra Vitamins added to compensate for loss on storage)

Dosage One tablespoonful two times daily or as directed by the physician

RUBRATON® PEDIATRIC **Elixir**

Vitamin B_{12} with Folic Acid and Iron Elixir
(FOR PEDIATRIC USE ONLY)

Each 5 ml (approximately 1 teaspoonful) contains

Cyanocobalamin	2 5 mcg
Folic Acid	0 25 mg
Ferric Ammonium Citrate (providing Iron 38 mg)	0 177 g
Alcohol	0 25 ml

Alcohol 5% v/v

(Extra Vitamins added to compensate for loss on storage)

Dosage For children above 1 year—1 teaspoonful two times daily or as directed by the physician

THERAGRAN® **Tablets**

Vitamins Tablets
(FOR THERAPEUTIC USE)

Each capsule shaped tablet contains

Vitamin A (as Acetate)	10 000	IU
Vitamin D	1 000	IU
Vitamin C (as Sodium Ascorbate)	150	mg
Niacinamide	100	mg
Thiamine Mononitrate (B_1)	10	mg
Riboflavine (B_2)	10	mg
Calcium Pantothenate	50	mg
Pyridoxine Hydrochloride (B_6)	3	mg
Cyanocobalamin (B_{12})	15	mcg
Vitamin E	25	IU

(Extra Vitamins added to compensate for loss on storage)

Dosage One tablet daily or as directed by the physician

THERAGRAN® PEDIATRIC DROPS **Liquid**

Multiple Vitamin Drops
(FOR PEDIATRIC USE ONLY)

Each ml contains

Vitamin A (as Palmitate)	3000	IU
Vitamin D	400	IU
Thiamine Hydrochloride (B_1)	1	mg
Vitamin B_2 (as Riboflavine 5 Phosphate Sodium)	1 5	mg
Pyridoxine Hydrochloride (B_6)	1 5	mg
Niacinamide	15	mg
Vitamin C	40	mg
d Panthenol	3	mg

(Extra Vitamins added to compensate for loss on storage)

Dosage For infants below one year — 1 ml once a day or as directed by the physician

THERAGRAN® SYRUP (For Children) **Syrup**

Multivitamin Tonic with Lysine and Iron
(FOR THERAPEUTIC USE)

Each 5 ml contains

Vitamin A (as Palmitate)	2500	IU
Vitamin D	200	IU
Thiamine Hydrochloride (B_1)	2 2	mg
Vitamin B_2 (as Riboflavine 5 Phosphate Sodium)	2 5	mg
Niacinamide	20	mg
Pyridoxine Hydrochloride (B_6)	1 5	mg
d Panthenol	5	mg
Cyanocobalamin (B_{12})	2 5	mcg
Vitamin C	40	mg
Lysine Mono hydrochloride	100	mg
Ferrous Gluconate	26	mg

In a pleasantly flavoured syrup base

(Extra Vitamins added to compensate for loss on storage)

Dosage One teaspoonful two times daily or as directed by the physician

THERAGRAN GR® (Geriatric Formula) **Tablets**

Vitamin Mineral Hormone Tablets
(FOR PROPHYLACTIC USE)

Each tablet contains

VITAMINS		
Vitamin A (as Acetate)	2500	IU
Vitamin D	200	IU
Vitamin C (as Sodium Ascorbate)	50	mg
Thiamine Mononitrate (B_1)	2	mg
Riboflavine (B_2)	3	mg
Niacinamide	26	mg
Pyridoxine Hydrochloride (B_6)	1 5	mg
Calcium Pantothenate	5	mg
Vitamin E	10	IU
Folic Acid	0 3	mg
Cyanocobalamin (B_{12})	1 0	mcg
MINERALS		
Potassium Iodide (equivalent to 0 1 mg Iodine)	0 13	mg
Dried Ferrous Sulphate (equivalent to 10 mg Iron)	34 0	mg
Copper Sulphate (equivalent to 1 0 mg Copper)	4 0	mg
Manganese Sulphate (equivalent to 1 0 mg Manganese)	2 8	mg
Magnesium Oxide (equivalent to 6 mg Magnesium)	10 0	mg
Zinc Sulphate (equivalent to 1 0 mg Zinc)	4 4	mg
HORMONES		
Ethinylestradiol	0 016	mg
Methyltestosterone	8 0	mg

(Extra Vitamins added to compensate for loss on storage)

Dosage One tablet daily or as directed by the physician

THERAGRAN M® **Tablets**

Vitamins Minerals Tablets
(FOR THERAPEUTIC USE)

Each tablet contains

VITAMINS		
Vitamin A (as Acetate)	10 000	IU
Vitamin D	1 000	IU
Vitamin C (as Sodium Ascorbate)	150	mg
Thiamine Mononitrate (B_1)	10	mg
Riboflavine (B_2)	10	mg
Niacinamide	100	mg
Pyridoxine Hydrochloride (B_6)	3	mg
Calcium Pantothenate	50	mg
Vitamin E	25	IU
Cyanocobalamin (B_{12})	15	mcg

MINERALS

Potassium Iodide (equivalent to 0 15 mg Iodine)	0 2 mg
Dried Ferrous Sulphate (equivalent to 12 mg Iron)	41 mg
Copper Sulphate (equivalent to 2 mg Copper)	8 mg
Manganese Sulphate (equivalent to 1 mg Manganese)	2 8 mg
Magnesium Carbonate (equivalent to 65 mg Magnesium)	270 mg
Zinc Sulphate (equivalent to 1 5 mg Zinc)	6 6 mg

(Extra Vitamins added to compensate for loss on storage)

Dosage One tablet daily or as directed by the physician

VIMGRAN® **Tablets**

Multiple Vitamins Minerals Tablets
(FOR PROPHYLACTIC USE)

Each tablet contains

VITAMINS

Vitamin A (as Acetate)	2500 IU
Vitamin D	200 IU
Thiamine Mononitrate (B_1)	2 mg
Riboflavine (B_2)	3 0 mg
Pyridoxine Hydrochloride (B_6)	1 5 mg
Cyanocobalamin (B_{12})	1 0 mcg
Calcium Pantothenate	5 0 mg
Niacinamide	25 0 mg
Vitamin C (as Sodium Ascorbate)	50 0 mg
Vitamin E	10 IU
Folic Acid	0 3 mg

MINERALS

Calcium Carbonate (equivalent to 100 mg Calcium)	250 mg
Ferrous Sulphate exsiccated (equivalent to 10 mg Iron)	34 mg
Potassium Iodide (equivalent to 0 15 mg Iodine)	0 2 mg
Potassium Sulphate (equivalent to 5 mg Potassium)	11 0 mg
Copper Sulphate (equivalent to 1 mg Copper)	4 mg
Manganese Sulphate (equivalent to 1 mg Manganese)	2 8 mg
Zinc Sulphate (equivalent to 1 5 mg Zinc)	6 6 mg
Magnesium Oxide (equivalent to 6 mg Magnesium)	10 mg

(Extra Vitamins added to compensate for loss on storage)

Dosage One tablet daily or as directed by the physician

The following products, containing vitamins, listed in this Product Reference Book, are presently not being manufactured.

1. Basiton Capsules
2 Engran Tablets
3. Navitol Malt Compound Syrup
4 Vigran with B_{12} Capsules

SARABHAI*

Medicines you can trust

SARABHAI CHEMICALS
A Division of Ambalal Sarabhai Enterprises Ltd.
BARODA 390 007

* Trademark of ASE Ltd

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SARABHAI*

PRODUCT REFERENCE BOOK

FOR THE MEDICAL PROFESSION

1983

SARABHAI CHEMICALS

(A Division of Ambalal Sarabhai Enterprises Ltd)

SARABHAI CHEMICALS

(A Division of Ambalal Sarabhai Enterprises Ltd)

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CONTENTS

Published by M L Prabhu for Sarabhai Chemicals, Shahibag House, 13, Walchand H Marg, Ballard Estate, Bombay 400 038 and printed at King of Kings, Chowpatty, Bombay 400 007

AMBISTRYN-S®

Sterile Powder

Streptomycin Sulphate

Streptomycin Sulphate is a sterile powder readily soluble in pyrogen-free water or sterile isotonic sodium chloride solution It is supplied in vials containing the equivalent of 0 75 g and 1 g pure streptomycin base

Indications and Dosage

TUBERCULOSIS

Daily 0 75-2 g for adults with severe constitutional reactions and particularly with extensive pneumonia miliary or meningeal tuberculosis

Intermittently 0 75 to 1 g twice weekly or every three days for adults without severe constitutional reactions or following adequate response to daily administration For children the average daily dose of streptomycin is 20 mg/kg given in divided amounts at 8- to 12 hour intervals

Type of Tuberculosis	*Treatment Duration*
pulmonary	up to 1 yr or more depending on clinical judgement and bacterial sensitivity tests
surgical pulmonary (streptomycin should not be used routinely in all thoracoplasty cases)	preoperatively – depends on patient s response postoperatively – depends on risk of tuberculous complications 4 8 wk for surgery in presence of stable pulmonary lesions
mucosal (bronchial tracheal laryngeal gastrointestinal otitic)	largely a matter of clinical judgement – palliative courses generally shorter than definitive
serosal (pleural including empyema pericardial peritoneal) genitourinary (other antimicrobial therapy may be used simultaneously to control coincident urinary infection) skeletal (bony articular cartilaginous synovial)	*inoperable* – several mo to 1 yr *operable* – at least 3 wk preoperatively and as long as needed postoperatively *palliative* – 1 2 wk
adenitis primary and secondary cutaneous sinuses and fistulae optic	*palliative* – only until desired result is achieved For adenitis until glands become impalpable or for 4 mo
acute haematogenous disseminated (miliary) routine lumbar punctures should be done periodically to detect development of meningitis which often occurs with miliary tuberculosis	at least 1 yr

NON TUBERCULOUS CONDITIONS

Conditions	*Total Daily Dose†*	*Treatment Duration*	*COMMENTS*
subacute bacterial endocarditis penicillin resistant	2 g (in divided doses q 8 12 h)	3 4 wk or longer depending on response	Perform *in vitro* tests for sensitivity periodically beginning before therapy Supplementary penicillin or other antibiotic therapy may be necessary
brucellosis with bacteraemia	1 5 3 g (in divided doses q 12 h)	14 days	In conjunction with a broad spectrum antibiotic such as tetracycline hydrochloride
peritonitis due to gram negative bacilli	2 2 5 g (in divided doses q 8 12 h)	7 14 days	Supplementary penicillin and sulphonamide therapy may be necessary since bacterial flora is complex
granuloma inguinale	3 g (in divided doses q 12 h)	7 14 days	
urinary tract infections due to susceptible organisms	1 2 5 g (in divided doses q 12 h)	5 7 days	Adequate surgical drainage and elimination of infective foci are essential Severe infections may require the higher dosage for 14 days Perform *n vitro* tests during treatment particularly when the clinical response is slow or unsatisfactory Local and constitutional symptoms may disappear without sterilization of urine
acute gonorrhoea	1 g as a single injection repeated if necessary		Penicillin is drug of choice give streptomycin only to those allergic or failing to respond to penicillin Where concomitant syphilis is suspected make darkfield examination before treatment and serologic tests monthly for 3 months

† *All dosages refer to mg or g equivalents of free base Some other therapeutic agent should be added or substituted if streptomycin resistant strains occur*

Contraindications Streptomycin is contraindicated in those persons who have shown hypersensitivity to it

Precautions The caloric stimulation test for vestibular function and audio metric tests are advisable during prolonged streptomycin therapy to detect signs of developing eighth nerve damage tests should be made before treatment is started and periodically thereafter Vestibular damage may be permanent although symptoms tend to disappear as the patient

adjusts and learns to compensate visually Auditory impairment is usually permanent

As with any antibiotic preparation prolonged use may result in an over growth of nonsusceptible organisms including fungi Constant observation of the patient is essential Should superinfection occur the drug should be discontinued and/or appropriate therapy instituted

Adverse Reactions Streptomycin in large doses produces vestibular disturbances There is evidence that streptomycin when used in lower doses for a prolonged period while treating pulmonary tuberculosis induces lesser vestibular disturbances

As with all products containing streptomycin these products should be used with caution during pregnancy due to the potential hazard of ototoxicity to the foetus Cases of vestibular and auditory damage to infants have been reported following treatment of the pregnant women with streptomycin

Pre existing renal impairment interferes with excretion producing high blood levels and increasing the risk of toxicity from streptomycin and other anti tuberculous agents In the presence of pre existing renal damage the dosage of anti tuberculous agents should be reduced to allow for drug retention the blood concentration of streptomycin should not exceed 20 to 25 mcg/ml plasma

Signs of kidney involvement (proteinuria cylindruria haematuria and occasional azotaemia) generally disappear on withdrawal of the drug Unless renal function is impaired changes in the urine are usually not a cause for interrupting therapy Pain and tenderness at the site of injection and skin eruptions may occur Skin or other allergic reactions can usually be controlled with antihistaminics but if they persist the drug should be withdrawn

Headache paraesthesias of the face and gastric disturbances may also occur Clinical judgement as to termination of therapy must be exercised when such side effects occur

Directions for Reconstitution of the Sterile Powder Dilute with Sterile Water for Injection or Sodium Chloride Injection in the following manner Loosen Powder Hold vial horizontally and rotate it while *slowly* directing the stream of diluent against the wall of the vial Shake vial vigorously after the diluent has been added

Add 2 ml or more diluent as desired to 0 75 g vial

The suggested maximum volume per injection is 2 ml For a concentration of 250 mg/ml add 3 7 ml diluent to the 1 g vial For a concentration of 500 mg/ml add 1 5 ml to the 1 g vial

Administration Streptomycin Sulphate should be given intramuscularly *Streptomycin Sulphate Injection should not be given intrathecally or intravenously because it contains a preservative*

Intramuscular injections are sometimes painful but pain is reduced if the following precautions are taken (1) Inject high in the upper outer quadrant of the buttock (2) Change the site for each injection (3) Insert needle deeply to avoid subcutaneous deposition inject slowly *Use 1%*

procaine hydrochloride in distilled water as diluent for streptomycin sulphate powder if necessary

Presentation Vials containing equivalent of 0 75 g and 1 g streptomycin base Boxes of 25 vials

Expiration date 39 months Stable at room temperature Sterile solutions freshly prepared from streptomycin powder may be kept at room temperature for 4 weeks without appreciable loss of potency These solutions may become discoloured on standing but this does not indicate any change which would prevent their use Discolouration will be reduced materially or prevented if the solutions are refrigerated

ANATENSOL® Tablets

Fluphenazine Hydrochloride

Anatensol Fluphenazine Hydrochloride is a trifluoromethyl fluphenazine derivative intended for the management of anxiety and tension states and severe mental disorders A highly potent behaviour modifier Anatensol offers the advantage of a sustained and prolonged action

Anatensol is available for oral administration as sugar-coated tablets of 1 mg

Action Laboratory and clinical studies have demonstrated that while the pharmacologic effects of fluphenazine are in general similar to those of other phenothiazines several important differences exist First fluphenazine is considerably more potent and has a more prolonged duration of action than either Siquil® (Triflupromazine Hydrochloride) or chlorpromazine Second because of its chemical structure hypotension may be less likely to occur than with some of the older phenothiazine derivatives nevertheless appropriate cautions should be observed particularly with the higher dosage See *Adverse Reactions and Precautions* Third fluphenazine appears to have less of a sedative effect than most other phenothiazines It does not potentiate central nervous system depressants and anaesthetics to the same degree as some other phenothiazines Moreover in many psychotic patients the drug seems to redirect the patient s activity rather than to suppress it

Anatensol has undergone clinical trials in the treatment of various mental and emotional disorders In both acute and chronically ill psychotic patients it has proved to be highly effective in modifying psychotic behaviour patterns and ameliorating such symptoms as agitation and delusions or hallucinations The prolonged action of fluphenazine constitutes an outstanding advantage permitting single daily administration of maintenance dosage in many patients

Experimental and clinical studies suggest that the phenothiazine derivatives act on the hypothalamus are believed to depress various components of the mesodiencephalic activating system which is involved in the control of basal metabolism and body temperature wakefulness vasomotor tone emesis and hormonal balance exert a peripheral autonomic effect in varying degrees However the site and mode of action of pheno

thiazine derivatives including fluphenazine have not been completely elucidated

Advantages

- sustained and prolonged action
- single daily dosage plan possible – optimal therapy for many patients
- maximal activity – most potent of available phenothiazines
- fewer toxic reactions than other phenothiazines
- side effects including extrapyramidal symptoms usually reversible by adjusting dosage to *lower therapeutic levels* and/or by using anti-Parkinsonism drugs
- effective in both acute and chronic patients
- strong antihallucinatory and antidelusional properties
- good patient acceptance – even in the elderly
- therapeutically effective without excessive sedation
- hypotension if it occurs rarely requires cessation of therapy
- maximum economy

Indications Anatensol tablets are of value in the alleviation of anxiety and tension complicating somatic disorders such as the premenstrual tension menopause gastrointestinal disturbances mild hypertension envrion mental stress tension headaches emotional stress psychoneurotic re actions management of agitation and emotional instability in the aged

Because of its marked ability to modify psychotic behaviour patterns Anatensol is also of particular usefulness in the management of psycho motor agitation and overt hostility frequently associated with such acute and chronic psychoses as schizophrenia mania psychoses due to organic brain disease mental deficiency and senile psychoses

Contraindications Phenothiazines are contraindicated in patients with suspected or established subcortical brain damage with or without hypothalamic damage since a hyperthermic reaction with temperatures in excess of 104 F may occur sometimes as late as 14 to 16 hours after drug administration if the drug is used in such patients If such a reaction should occur total body ice packing is recommended antipyretics may also be useful

Phenothiazine compounds should not be used in patients receiving large doses of hypnotics and should be used with caution in patients with a history of convulsive disorders since grand mal convulsions have been known to occur

Patients with special medical disorders such as mitral insufficiency or phaeochromocytoma and patients who have exhibited idiosyncrasy to other centrally acting drugs may experience severe reactions to pheno thiazine compounds

Caution The use of phenothiazines as a class is associated with different degrees of drowsiness Usually under the recommended dose this is almost absent with fluphenazines All the same it is worthwhile to remember that engine crews vehicle drivers and workers in workshops with fast moving parts are advised not to use these drugs while on duty unless recommended and approved by the physician attending on them

Adverse Reactions and Precautions The most frequently reported side effects associated with phenothiazine administration are reversible extrapyramidal symptoms including Parkinsonism dystonia dyskinesia akathisia oculo gyric crises opisthotonos and hyper reflexia Although these reactions may be alarming all are reversible and disappear if dosage is lowered or therapy is temporarily discontinued More rapid reversal may be achieved by administration of anti Parkinsonian drugs or intravenous Caffeine and Sodium Benzoate Injection

Liver damage as manifested by jaundice or biliary stasis may be encoun tered Blood dyscrasias including leucopenia agranulocytosis thrombo cytopenic purpura eosinophilia and pancytopenia have been observed with phenothiazine derivatives For this reason routine blood counts are advisable during therapy

The patient should be observed for any soreness of the mouth gums or throat or any symptoms of upper respiratory infection If these symptoms and the confirmatory leucocyte count indicates cellular depression therapy should be discontinued and other appropriate measures should be insti tuted immediately Skin disorders such as itching erythema urticaria and even exfoliative dermatitis have been reported with phenothiazine com pounds The possibility of anaphylactoid reactions occurring in some patients should be borne in mind

Peripheral oedema endocrine disturbances such as abnormal lactation and autonomic reactions including nausea anorexia salivation polyuria perspiration dry mouth headache and constipation may occur Autonomic effects can usually be controlled by reducing or temporarily discontinuing dosage Drowsiness or lethargy if they occur may necessitate a reduction in dosage the induction of a catatonic like state has been known to occur with dosage far in excess of the recommended amounts As with other phenothiazine compounds reactivation of psychotic processes may be encountered

Hypotension is rarely a problem with fluphenazine however patients with pheochromocytoma cerebral vascular or renal insufficiency or a severe cardiac reserve deficiency such as mitral insufficiency appear to be parti cularly prone to hypotensive reactions with phenothiazine compounds and should be observed closely when the drug is administered If severe hypo tension should occur supportive measures including the use of intravenous vasopressor drugs should be instituted immediately Levarterenol Bitartrate Injection is the most suitable drug for this purpose *epinephrine should not be used* since phenothiazine derivatives have been found to reverse its action resulting in a further lowering of blood pressure Psychotic patients on large doses of a phenothiazine drug who are undergoing sur gery should be watched carefully for possible hypotensive phenomena reduced amounts of anaesthetics or central nervous system depressants may be required

Although this is not a general feature of fluphenazine potentiation of cen tral nervous system depressants (opiates analgesics antihistamines bar biturates alcohol) may occur The effects of atropine may be potentiated in some patients receiving fluphenazine

Overdosage See *Adverse Reactions and Precautions* In the event of intentional or accidental overdosage there is a possibility that dyskinetic manifestations akathisia and Parkinsonism may appear especially if the drug has been taken to excess over a period of days or weeks Hypotension blurred vision dizziness or jitteriness may also occur

Overdosage is treated symptomatically and supportively If the patient is conscious prompt gastric lavage dilution of the stomach contents to delay absorption or stimulation of vomiting should be attempted In the conscious or unconscious patient an open airway should be maintained to preclude the possibilty of respiratory difficulty Drug-induced extrapyramidal symptoms are generally amenable to anti-Parkinsonism drugs In severe hypotension the standard measures for management of circulatory shock should be instituted e g vasoconstrictors and/or fluids administered intravenously l Norepinephrine bitartrate is recommended as a vaso constrictive agent in this case

Administration and Dosage

Anxiety and Tension States In anxiety and tension states the suggested dosage for *adults* is 1 mg both for initial and maintenance therapy as a single dose For severe conditions 1 mg can be given twice daily to be followed by a maintenance dose of 1 mg daily

Mental Disorders in Adults Depending on severity and duration of symptoms total daily dosage for *adult* psychotic patients may range initially from 2 5 to 10 mg and should be divided and given at 6 to 8 hour intervals

The smallest amount that will produce the desired results must be carefully determined for each individual since optimal dosage levels of this potent drug vary from patient to patient Treatment is best instituted with *low initial dosage* which may be increased if necessary until the desired clinical effects are achieved Daily dosages exceeding 20 mg should be used with caution When symptoms are controlled dosage can generally be reduced gradually to daily maintenance doses of 1 to 5 mg often given as a single daily dose Continued treatment is needed to achieve maximum therapeutic benefits further adjustments in dosage may be necessary during the course of the therapy to meet the patient s requirements

For *geriatric* patients the suggested starting dose is 1 to 2 5 mg daily adjusted according to the response of the patient

Presentation Sugar coated tablets of 1 0 mg Strips of 10 tablets and boxes of 10 strips of 10 s

ANATENSOL® DECANOATE INJECTABLE — Parenteral Solution

Fluphenazine Decanoate Injection

Anatensol Decanoate is an esterified trifluoromethyl phenothiazine derivative It is a highly potent antipsychotic agent with a markedly extended duration of action available for intramuscular administration in 1 ml vials providing 25 mg fluphenazine decanoate in a sesame oil vehicle w 1 2% (w/v) benzyl alcohol as a preservative

Indications Anatensol Decanoate is indicated in the management of psychotic disorders including schizophrenia mania and organic brain syndrome It is of particular value in the treatment of chronic schizophrenia The drug often alleviates such target symptoms such as hallucinations delusions confusion and withdrawal It is not only useful in the hospital milieu but is unparalleled because of its long duration of action in the long term maintenance therapy of chronically psychotic patients who are amenable to out patient therapy

Medical Rationale The basic effects of fluphenazine decanoate appear to be no different from those of fluphenazine hydrochloride The only exception to this is a prolonged duration of action The esterification of fluphenazine with decanoic acid markedly prolongs the drug s duration of effect without reducing its activity The onset of action generally appears between 24 and 72 hours after injection and the effects of the drug on psychotic symptoms become significant within 49 to 96 hours The therapeutic acti vity then continues for 1 to 4 weeks To date Anatensol Decanoate is the longest acting phenothiazine preparation available

Like all phenothiazine derivatives fluphenazine decanoate appears to act on the hypothalamus depressing various components of the mesodience phalic activating system which is involved in the control of basal meta bolism and body temperature wakefulness vasomotor tone emesis and hormonal balance In addition the phenothiazines exert a peripheral auto nomic effect in varying degrees However the site and mode of action of the phenothiazines have not been completely elucidated

Fluphenazine and its ester derivatives differ from other phenothiazines in several respects fluphenazine and its esters are more potent on a milligram basis appear to be less sedating and have less potentiating effect on central nervous system depressants and anaesthetics than do some of the older phenothiazines to produce hypotension [1] (Nevertheless appropriate cautions should be observed – see *Precautions and Adverse Reactions*)

A long acting parenteral antipsychotic agent is an invaluable aid both to the psychotic patient and to those who are responsible for him Fluphena zine decanoate reduces hallucinations delusions confusion withdrawal and to lesser degree hostility and agitation In general the psychotic patient becomes more cooperative less withdrawn more responsive to social situations and more subjective to psychotherapy or other nonchemo therapeutic measures In the hospital the nursing staff is relieved of the need for daily or even more frequent administration of drugs to a class of patients who may be difficult to treat and who frequently dispose of oral medication without swallowing it In out patient care where constant supervision is rarely feasible the longer interval between the injections reduces the problem of providing adequate maintenance dosage for pa tients who often fail to continue daily oral medication and consequently suffer frequent severe recurrences of acute psychotic episodes Because maintenance medication can be more easily assured through the use of Anatensol Decanoate it may be possible to release an increasing number of patients from custodial hospital care to an out-patient status

Anatensol Decanoate produces far fewer extrapyramidal side effects and a larger proportion of milder extrapyramidal side effects than any other

fluphenazine product A study conducted to determine the effects of Anatensol Decanoate revealed that out of 501 patients 314 (62 7%) did not exhibit any extrapyramidal side effects Out of the 187 patients who did show a variety of extrapyramidal side effects 94 (50%) exhibited symptoms of only mild severity

Adverse Effects Central Nervous System The side effects most frequently reported with phenothiazine compounds and other antipsychotic agents are extrapyramidal symptoms such as pseudo Parkinsonian (tremor rigidity etc) akathisia They are *usually reversible* however a persistent pseudo-Parkinsonian syndrome may develop after a prolonged administration of phenothiazines This syndrome is characterized by rhythmic stereotyped dyskinetic involuntary movements (particularly of the face mouth tongue and jaw) which resemble the facial grimaces of encephalitis These may be accompanied by the choreiform movements of the limbs In these chronic cases the symptoms may persist after drug withdrawal and ap pear to be irreversible in some patients Anti Parkinsonian agents may not be of benefit in these instances The risk of developing this persistent syndrome appears to be greatest in elderly female patients with organic brain disease or damage who have been receiving fairly large doses of phenothiazines for a prolonged period

Extrapyramidal reactions may be alarming and the patient should be fore warned and reassured These reactions can usually be controlled by ad ministration of anti-Parkinsonian drugs and if necessary reduction in dosage

A reduction in dosage or symptomatic treatment may be necessary to relieve drowsiness lethargy or depression if they occur As with other phenothiazines reactivation or aggravation of psychotic processes may be encountered Phenothiazine derivatives have been known to cause rest lessness excitement or bizarre dreams in some patients

Autonomic Nervous System Hypotension has rarely presented a problem with fluphenazines However patients with pheochromocytoma cerebral vascular or renal insufficiency appear to be particularly prone to hypoten sive reactions with phenothiazines they should therefore be observed closely when the drug is administered If severe hypotension should occur supportive measures including the use of intravenous vasopressor drugs should be instituted immediately Levarterenol Bitartrate (Levophed) is the most suitable drug for this purpose *epinephrine should not be used* since phenothiazine derivatives have been found to reverse its action further lowering the blood pressure

Hypertension and fluctuations in blood pressure have been reported with phenothiazines

Autonomic reactions including nausea and loss of appetite salivation polyuria perspiration dry mouth headache and constipation may occur Auto nomic effects can usually be controlled by reducing or temporarily interrupting dosage In some patients phenothiazine derivatives have caused blurred vision glaucoma bladder paralysis faecal impaction paralytic ileus tachycardia or nasal congestion

Metabolism and Endocrine System Weight change peripheral oedema abnormal lactation gynaecomastia menstrual irregularities false results on pregnancy tests impotency in men and increased libido in women have all been known to occur in some patients on phenothiazine therapy

Allergic Reactions Skin disorders such as itching erythema urticaria seborrhoea photosensitivity eczema and even exfoliative dermatitis have been reported with phenothiazine derivatives

Other reactions Sudden unexpected and unexplained deaths have been reported in hospitalized psychotic patients receiving phenothiazines Previous brain damage or seizures may be predisposing factors high doses should be avoided in known seizure patients [2] Several patients have shown sudden flare-ups of psychotic behaviour patterns shortly before death Autopsy findings in these cases have usually revealed acute ful minating pneumonia or pneumonitis aspiration of gastric contents or intra myocardial lesions [2 4 5]

Although this is not a general feature of fluphenazine potentiation of cen tral nervous system depressants (opiates analgesics antihistamines bar biturates alcohol) may occur – see *Precautions* for patients undergoing surgery The effects of atropine may also be potentiated in some patients

The following adverse reactions have also occurred with phenothiazine derivatives Hypotension severe enough to cause fatal cardiac arrest al tered electrocardiographic and electroencephalographic tracings altered cerebrospinal fluid proteins cerebral oedema disturbances of body tem perature (hypo and hyperthermia) potentiation of reactions to extreme heat potentiation of reactions to phosphorus insecticides asthma laryn geal oedema angioneurotic oedema and pigmentary retinopathy with long term use skin pigmentation and lenticular and corneal opacities have also occurred

Injections of fluphenazine decanoate are extremely well tolerated local tissue reactions occurring only rarely

Precautions Fluphenazine decanoate should be used cautiously in patients who have had cholestatic jaundice Liver damage rarely manifested by cholestatic jaundice may be encountered during therapy [2] Treatment should be discontinued if this occurs Alterations in cephalin flocculation or alkaline phosphatase and/or increased thymol turbidity (with or without leuco cytosis) sometimes accompanied by abnormalities in other liver function tests have been reported in patients receiving fluphenazine decanoate who have had no clinical evidence of liver damage This however is not uncommon with phenothiazine therapy [3]

Renal functions of patients on long term therapy should be monitored if BUN (Blood Urea Nitrogen) becomes abnormal treatment may have to be discontinued

Routine blood counts are advisable during therapy since rare instances of blood dyscrasias including leucopenia agranulocytosis thrombocytopenic or non-thrombocytopenic purpura eosinophilia and pancytopenia have been reported with some other phenothiazine derivatives If any soreness of the mouth gums or throat or any symptoms of upper respiratory

infection occur and a leucocyte count confirms cellular depression therapy should be discontinued and appropriate measures instituted immediately

Phenothiazine should be used with caution in patients with a history of convulsive disorders since grand mal convulsions have been known to occur

Patients with special medical disorders such as mitral insufficiency or pheochromocytoma and patients who have exhibited idiosyncrasy to other centrally acting drugs may experience severe reactions to phenothiazine compounds

Anaphylactoid reactions may occur in some patients Fluphenazine deca noate should be used cautiously in patients with a history of skin rashes or other allergic reactions to another phenothiazine compound because of the possibility of cross-sensitivity

When undergoing surgery Psychotic patients receiving large doses of phenothiazine preparation should be watched carefully for possible hypo tensive phenomena Moreover it should be remembered that a reduction in dosage of anaesthetics or central nervous system depressants may be required

As with any phenothiazine the physician should be alert to the possible development of silent pneumonias in patients under treatment with flu phenazine decanoate

Fluphenazine decanoate should be administered under the direction of a physician experienced in the clinical use of psychotropic drugs particularly phenothiazine derivatives Furthermore facilities should be available for periodic checking of the hepatic function renal function and the blood picture

Contraindications Phenothiazines are contraindicated in patients with suspected or established subcortical brain damage with or without hypothalamic damage since a hyperthermic reaction with temperatures in ex cess of 104 F may occur in such patients Sometimes this reaction may not occur until 14 to 16 hours after drug administration If it does occur total body ice packing is recommended antipyretics may also be useful

Phenothiazine should not be used in patients receiving large doses of hypnotics (see *Precautions* for patients undergoing surgery)

As with other phenothiazines Anatensol Decanoate Injectable (Fluphenazine Decanoate Injection) is contraindicated in comatose or severely depressed states

The presence of blood dyscrasia liver disease or renal insufficiency pre cludes the use of fluphenazine decanoate

Fluphenazine decanoate is not intended for use in children under 12 years of age

Administration and Dosage The usual adequate dosage of fluphenazine de canoate is 25 mg (1 ml) every 3 to 4 weeks If necessary adjustments in the amount and the dosage interval may be made in accordance with the patient s response

The optimal amount of the drug and the frequency of the administration must be determined for each patient since dosage requirements have been found to vary with clinical circumstances as well as with individual response to the drug Although in a large series of patients the optimal dose was usually 25 mg (1 ml) every 3 to 4 weeks the amount required ranged from 12 5 to 75 mg (0 5 to 3 ml) The interval between the doses ranged from 2 weeks to 5 weeks in most instances but some patients required doses as often as once every 3 days for the first few injections while the response to a single dose was found to last 6 weeks or longer in a few patients on maintenance therapy

For *patients who have had no previous therapy* it is advisable to initiate treatment with an oral antipsychotic agent such as Anatensol Tablets (Fluphenazine Hydrochloride) – see package insert accompanying this pro duct for complete information When optimal response has been esta blished fluphenazine decanoate should be administered at 25 mg (1 ml) every 3 to 4 weeks In switching over to fluphenazine decanoate the quick acting antipsychotic agent should be administered concurrently for 3 days and then discontinued

For *patients on short acting phenothiazine drugs* fluphenazine deca noate at 25 mg (1 ml) every 3 to 4 weeks should be adequate The previous antipsychotic agent should be administered concurrently for 3 days and then discontinued

For *patients on fluphenazine enanthate therapy* the equivalent dosage of fluphenazine decanoate will provide longer interval between admini strations

Poor risk patients (those with known hypersensitivity to phenothiazine or with disorders that predispose to undue reactions) Therapy should be initiated cautiously with a quick-acting oral antipsychotic agent (such as fluphenazine hydrochloride – see package insert accompanying product for complete information) When optimal response has been established fluphenazine decanoate should be administered at 25 mg (1 ml) every three weeks In switching over to fluphenazine decanoate the quick acting antipsychotic agent should be administered concurrently for 3 days and then discontinued

Presentation Anatensol Decanoate Injectable is supplied in 1 ml vials providing 25 mg fluphenazine decanoate

Note Anatensol Decanoate Injectable should be administered intra muscularly A dry needle and syringe should be used Use of a wet needle or syringe may cause the solution to become cloudy Store in a cool dark place

Expiration date 18 months

References 1 Himwich H Comparative values of phenothiazine drugs Presented before the American Psychiatric Association Regional Research Conference Little Rock Ark February 1959

2 Hollister L E Adverse Reactions to Phenothiazines J A M A 189 311 (1964)

3 Bloom J B *et al* Effect on the Liver of Long Term Tranquilizing Medication Am J Psychiat 121 788 (1965)

4 Lapolla A and Nash L R Sudden Death in Mental Institutions Presented before the American Psychiatric Association Western Meeting Hawaii Aug 1965

5 Richardson H L *et al* Intramyocardial Lesions in Patients Dying suddenly and unexpectedly J A M A 195 254 (1966)

ANATENSOL® ENANTHATE INJECTABLE — Parenteral Solution

Fluphenazine Enanthate

Anatensol Enanthate Injectable (Fluphenazine Enanthate) is an esterified trifluoromethyl phenothiazine derivative chemically designated as 4-3-2 (Trifluoromethyl)-phenothiazine 10 yl propyl-I piperazine-ethanol heptano ate (enanthate) It is a highly potent and antipsychotic agent with a markedly extended duration of effect available for parenteral administration in vials providing 25 mg fluphenazine enanthate per ml in a sesame oil vehi cle with 1 5% benzyl alcohol as a preservative

Action Phenothiazine derivatives appear to act on the hypothalamus depressing various components of the mesodiencephalic activating system In addition the drugs exert a peripheral autonomic effect in varying degrees However the site and mode of action of the phenothiazine derivatives have not been completely elucidated

In the treatment of psychotic disorders fluphenazine alleviates many of the psychotic symptoms The drug is primarily effective in reducing hostility anxiety agitation and hyperactivity In general the psychotic patient becomes more cooperative more responsive to social situations and more subject to basic therapy

Fluphenazine differs from the other phenothiazine derivatives in several respects it is more potent on a milligram to milligram basis it has a potentiating effect on central nervous system depressants and anaesthetics than do some of the phenothiazines and appears to be less sedating and it is less likely than some of the older phenothiazines to produce hypotension (nevertheless appropriate cautions should be observed – see section on *Side Effects and Precautions*)

The esterification of fluphenazine markedly prolongs the drug s duration of effect without unduly extenuating its beneficial action The onset of action generally appears between 24 to 72 hours after injection and the effects of the drug on psychotic symptoms become significant within 48 to 96 hours Amelioration of symptoms then continues for 1 to 3 weeks or longer with an average duration of effect of about 2 weeks

A long-acting parenteral behaviour modifier provides several advantages in the treatment of psychotic patients In hospital the nursing staff is relieved of the need for daily or even more frequent administration of drugs to a class of patients who by the nature of their disorder may be difficult to treat and who frequently dispose of oral medication without swallowing it In out-patient care where constant supervision is rarely

feasible a bi weekly injection reduces the problem of providing adequate maintenance dosage for possibly erratic patients who often fail to continue with daily oral medication and consequently suffer frequent severe recur rence of acute psychotic episodes Because maintenance medication can be more easily assured through the use of Anatensol Enanthate Injectable (Fluphenazine Enanthate) it may be possible to release an increasing number of patients from custodial hospital care to an out patient status

Indications Anatensol Enanthate Injectable (Fluphenazine Enanthate) is indi cated principally in schizophrenia mania and organic brain disease The drug alleviates such symptoms as agitation hostility and anxiety which are often associated with psychoses Anatensol Enanthate Injectable (Fluphenazine Enanthate) finds useful application not only in the hospital milieu but also in the long term maintenance therapy of chronically psycho tic pat ents who are treatable on an out patient basis

Containdications Phenothiazines are contraindicated in patients with suspect ed or established subcortical brain damage with or without hypothalamic damage since a hyperthermic reaction with temperatures in excess of 104 F may occur in such patients sometimes not until 14 to 16 hours after drug administration Total body ice packing is recommended for such a reaction antipyretics may also be useful Phenothiazine compounds should not be used in patients receiving large doses of hypnotics and should be used with caution in patients with a history of convulsive dis orders since grand mal convulsions have been known to occur

Patients with special medical disorders such as mitral insufficiency or pheochromocytoma and patients who have exhibited idiosyncrasy to other centrally acting drugs may experience severe reactions to phenothiazine compounds Fluphenazine enanthate is not intended for use in children under 12 years of age

Side Effects and Precautions The most frequently reported side effects asso ciated with phenothiazine administration are reversible extrapyramidal symptoms including Parkinsonism dystonia dyskinesia akathisia oculo gyric crises opisthotonos and hyper reflexia Although these reactions may be alarming all are reversible and can usually be controlled by admini stration of anti Parkinsonian drugs such as Tri hexyphenidyl hydrochloride or intravenous Caffeine and Sodium Benzoate Injection and by subsequent reduction in dosage

Liver damage as manifested by jaundice or biliary stasis may be encoun tered Blood dyscrasias including leucopenia agranulocytosis thrombo cytopenic purpura eosinophilia and pancytopenia have been observed with phenothiazine derivatives For this reason routine blood counts are advisable during therapy The patient should be observed for any soreness of the mouth gums or throat or any symptoms of upper respiratory infec tion If these symptoms occur and confirmatory leucocyte count indicates cellular depression therapy should be discontinued and other appropriate measures should be instituted immediately

Peripheral oedema endocrine disturbances such as abnormal lactation and autonomic reactions including nausea and loss of appetite salivation poly uria perspiration dry mouth headache and constipation may occur Auto

nomic effects can usually be controlled by reducing or temporarily discontinuing dosage Drowsiness or lethargy if they occur may necessitate a reduction in dosage the induction of catatonic like state has been known to occur with dosages far in excess of the recommended amounts

Hypertension and fluctuations in blood pressure have been reported with fluphenazine enanthate Hypotension has rarely presented a problem with fluphenazine However patients with pheochromocytoma cerebral vascular or renal insufficiency or a severe cardiac reserve deficiency such as mitral insufficiency appear to be particularly prone to hypotensive reactions with phenothiazine compounds and should therefore be observed closely when the drug is administered If severe hypotension should occur supportive measures including the use of intravenous vasopressor drugs should be instituted immediately Levarterenol Bitartrate (Levophed) is the most suitable drug for this purpose *epinephrine should not be used* since phenothiazine derivatives have been found to reverse its action resulting in a further lowering of blood pressure Psychotic patients on large doses of phenothiazine drugs who are undergoing surgery should be watched carefully for possible hypotensive phenomena Moreover it should be remembered that reduced amounts of anaesthetics or central nervous system depressants may be required

Although this is not a general feature of fluphenazine potentiation of central nervous system depressants (opiates analgesics anti histamines barbiturates alcohol) may occur The effects of atropine may be potentiated in some patients receiving fluphenazine

Renal function of patients on long term therapy should be monitored if BUN (Blood Urea Nitrogen) becomes abnormal treatment should be discontinued

Autonomic reactions including nausea and loss of appetite salivation polyuria perspiration dry mouth headache and constipation may occur Autonomic effects can usually be controlled by reducing or temporarily discontinuing dosage

Allergic Reactions Skin disorders such as itching erythema urticaria seborrhoea photosensitivity eczema and even exfoliative dermatitis have been reported with phenothiazine derivatives The possibility of anaphylactoid reactions occurring in some patients should be borne in mind

Others Sudden unexpected and unexplained deaths have been reported in hospitalized psychotic patients receiving phenothiazines Previous brain damage or seizures may be predisposing factors high doses should be avoided in known seizure patients Several patients have shown sudden flare ups of psychotic behaviour patterns shortly before death Autopsy findings have usually revealed acute fulminating pneumonia or pneumonitis aspiration of gastric contents or intramyocardial lesions

The following adverse reactions have also occurred with phenothiazine derivatives hypotension severe enough to cause fatal cardiac arrest altered electrocardiographic and electroencephalographic tracings altered cerebrospinal fluid proteins cerebral oedema potentiation of heat and of phosphorous insecticides asthma laryngeal oedema angioneurotic oedema and pigmentary retinopathy with long term use – skin pigmentation and lenticular and corneal opacities

Injection of fluphenazine enanthate is extremely well tolerated local tissue reactions occurring only rarely

Dosage The usual dose of Anatensol Enanthate Injectable (Fluphenazine Enanthate) is 25 mg (1 ml) every two weeks given intramuscularly or sub cutaneously Individual dose requirements vary however and may range from 12 5 to 100 mg (0 5 to 4 ml) given at intervals of 1 to 3 weeks The amount and frequency of dosage should therefore be adjusted in accordance with patient response

Anatensol Enanthate Injectable (Fluphenazine Enanthate) may be given for initial as well as for maintenance therapy

Presentation Anatensol Enanthate Injectable is supplied as multiple dose in 2 ml vials

Note A dry needle and syringe should be used Use of a wet needle or syringe may cause the solution to become cloudy Store in a cool dark place

Expiration date 18 months

ASCORBICIN® Tablets

ASCORBICIN® 500 mg Tablets

Ascorbic Acid — Vitamin C

Ascorbicin is Ascorbic Acid (Vitamin C)

In the body vitamin C plays the role of general activator of metabolic processes In particular it regulates intracellular respiration and metabolism stimulates the maturation of elements of the blood (erythrocytes leucocytes and thrombocytes) the formation of interstitial substance (collagenous fibres of the connective tissue dentine ossein) and defence mechanisms against infections and intoxications (by inactivation of toxins formation of antibodies and alexins)

Indications Ascorbicin is indicated in the treatment of vitamin C deficiency Ascorbicin is also indicated for the prevention or treatment of scurvy or where there is a pathologic interference with its assimilation in amounts necessary for the preservation of health Ascorbicin is also of value where dental caries pyorrhoea gum infections anorexia anaemia under nutrition increased capillary fragility or other conditions result from a deficiency of vitamin C Given before and after surgery Ascorbicin aids in the healing of wounds in patients with clinical or subclinical vitamin C deficiency

Dosage Orally 1 or more tablets daily as directed by the physician

Presentation Ascorbicin 250 mg Tablets Bottles of 100
Ascorbicin 500 mg Tablets Strips of 10 tablets and boxes of 10 strips of 10 s

Expiration date 24 months

AVEDAN† Tablets

Analgesic Compound

Avedan is a rapid-acting analgesic and antipyretic compound containing in addition to aspirin and caffeine N acetyl-p aminophenol (paracetamol) the chief active metabolite of acetanilide and acetophenetidin

Each Avedan Tablet contains

Acetyl p aminophenol	125 mg
Aspirin	230 mg
Caffeine	30 mg

Advantages With two Avedan tablets there is a marked rise in the pain threshold within 30 minutes with a peak effect in about 2½ hours – analgesia is maintained for about 4 hours Avedan is nonaddicting

Indications Avedan is particularly useful for fast temporary relief of neuralgic and musculoskeletal pain more specifically for pain in such conditions as simple headache migraine dysmenorrhoea common colds and grippe myalgia neuralgia bursitis sinusitis and after dental extractions and minor surgery

Precautions Avedan should not be used for more than 10 days and should not be administered to children under 6 years unless directed by the physi cian Keep it out of the reach of children

Dosage Adults 1 or 2 tablets with water May be repeated every 2 hours but not to exceed 12 tablets in 24 hours

Presentation Strips of 10 tablets and boxes of 10 strips of 10 s

AVEDAN† PLUS Tablets

Analgesic Compound

Each Avedan Plus Tablet contains

Acetyl p aminophenol	125 mg
Aspirin	350 mg
Caffeine	30 mg

Advantages Avedan Plus is a rapidly acting analgesic and antipyretic compound containing in addition to aspirin and caffeine a strong and safe analgesic Acetyl p aminophenol With oral administration of one tablet of Avedan Plus there is marked rise in the pain threshold within 30 minutes and reaches its peak in about 2½ hours Its effect is maintained for about 4 hours

Indications Avedan Plus is a strong analgesic particula ly useful for fast tem porary relief of neuralgic and musculoskeletal pain more specifically for pain in such conditions as simple headache migraine dysmenorrhoea common cold and grippe myalgia neuralgia bursitis sinusitis after dental extractions and minor surgery

Precautions Avedan Plus should not be used for more than 10 days and should not be administered to children under 6 years unless directed by the physi-cian Keep it out of the reach of children

Dosage Adults 1 or 2 tablets with water May be repeated every 2 hours but not to exceed 12 tablets in 24 hours

Presentation Strips of 10 tablets and boxes of 10 strips of 10 s

BASITON® — Capsules

B Complex Vitamins Yeast Folic Acid and Vitamin B_{12}

Basiton Capsules contain important B Complex Vitamins plus Yeast Folic Acid and Vitamin B_{12} for oral administration The administration of a vitamin supplement containing the B Complex Vitamins including Vitamin B_{12} helps assure more effective protection against B Complex deficiencies

Each Basiton Capsule contains

Vitamin B_1 (Thiamine Mononitrate)	2 0 mg
Vitamin B_2 (Riboflavine)	2 0 mg
Niacinamide	15 0 mg
Vitamin B_6 (Pyridoxine Hydrochloride)	0 125 mg
Calcium Pantothenate	2 0 mg
Brewer s Yeast	100 0 mg
Vitamin B_{12}	2 0 mcg
Folic Acid	0 134 mg

Indications Basiton Capsules as a dietary supplement are useful in guarding against deficiencies of B Complex Vitamins in persons who do not or cannot consume adequate diets

Dosage One to four capsules daily

Presentation Bottles of 25 and 100 capsules

Note Keep away from excessive heat

Expiration date 24 months

BASITON® FORTE INJECTION — Parenteral Solution

Stress B Complex Vitamins

Basiton Forte Injection is a formulation of Stress B Complex Vitamins for intramuscular use It contains seven physiologically important and therapeutically useful members of the B Complex Vitamins and provides high potency B Complex therapy Basiton Forte Injection is available as a special pack wherein the Vitamin B_{12} is given separately in an ampoule Before use the contents of the ampoule have to be added to the vial to give a total volume of 5 ml

Each ml of the reconstituted solution supplies

Vitamin B_{12} (Cyanocobalamin)	50 mcg
Vitamin B_1 (Thiamine Mononitrate)	50 mg
Vitamin B_2 (Riboflavine)	5 mg
Niacinamide	100 mg
Vitamin B_6 (Pyridoxine Hydrochloride)	5 mg
Panthenol	5 mg
Choline (as chloride)	25 mg

Indications Basiton Forte Injection contains all the major factors of vitamin B Complex in therapeutic amounts it is useful for the vitamin B Complex deficiency states met with in clinical practice Deficiency of a single factor of B Complex is relatively rare without a latent deficiency of other B Com plex factors also Hence Basiton Forte Injection is indicated for the treat ment of vitamin B Complex deficiencies These can be manifested as glossitis stomatitis ulcers of the mucous membranes of mouth cheilosis conjunctivitis photophobia epiphora scleral injection vomiting anorexia diarrhoea neuritis paraesthesias tenderness of calf muscles weakness fatigue vague neuritic pain pellagrous dermatitis burning foot syndrome etc It is also useful in debility during convalescence vitamin B Complex deficiency due to broad spectrum antibiotic therapy chronic debilitating diseases and diabetes mellitus

Administration of Basiton Forte Injection provides for the increased require ments of vitamin accompanying alcoholism thyrotoxicosis serious illness or tissue damage caused by injury burns excessive radiation or surgery Postoperatively Basiton Forte Injection therapy is recommended in the presence of anorexia or vomiting particularly for patients receiving infu sions of saline or glucose as such infusions may cause rapid depletion of water soluble vitamins by increasing their rate of urinary excretion More over many of the B Complex Vitamins form enzymes essential for the oxidation of glucose and infusions of glucose solutions may deplete tissue stores of B vitamins Since B vitamins are also concerned with protein and amino acid metabolism liberal quantities of the vitamin B Complex should be given to patients receiving amino acid or protein preparations parenter ally

Basiton Forte Injection is specially indicated in severe B Complex defi ciencies particularly in patients who cannot tolerate oral medication or in whom there is evidence of poor gastrointestinal absorption

Advantages

- contains seven physiologically important and therapeutically useful members of B Complex in high potency
- combats even severe B Complex deficiencies particularly in patients who cannot tolerate oral medication or in whom there is evidence of poor gastrointestinal absorption
- available as a special pack wherein the vitamin B_{12} is given separately in an ampoule

Administration and Dosage Before use inject the contents of the ampoule into the vial and mix properly One ml intramuscularly once or twice a day as may be decided by the physician

Reconstituted solution should be used up during the period required to complete the recommended course of injection

Presentation Basiton Forte Injection is available as a special pack wherein the vitamin B_{12} is given separately in an ampoule Before use the contents of the ampoule have to be added to the vial to give a total volume of 5 ml

Expiration date 15 months

BASITON® FORTE Tablets

Vitamin B Complex with Vitamin C

Basiton Forte Tablets Vitamin B Complex with Vitamin C for oral use supply high dosage of all essential B Complex vitamins including folic acid and vitamin B_{12} in addition Basiton Forte Tablets also contain therapeutic dosage of vitamin C

Each Basiton Forte Tablet contains

Vitamin B_1 (Thiamine Mononitrate)	10 mg
Vitamin B_2 (Riboflavine)	10 mg
Vitamin B_6 (Pyridoxine Hydrochloride)	2 mg
Niacinamide	100 mg
Calcium Pantothenate	50 mg
Vitamin B_{12} (Cyanocobalamin)	4 mcg
Vitamin C (as Sodium Ascorbate)	300 mg
Folic Acid	1 5 mg

Indications Basiton Forte Tablets contain all the major water soluble vitamins Basiton Forte Tablets are not ony useful for prophylaxis and treatment of vitamin B Complex deficiencies but also for the prevention and treatment of concurrent vitamin C deficiency Basiton Forte Tablets are specially useful whenever stress formula vitamins are indicated as after broad spectrum antibiotic therapy chronic debilitating diseases diabetes mellitus hepatic diseases pregnancy and lactation fractures and chronic alcoholism The symptoms of water soluble vitamin deficiencies are often seen in acute or chronic malnutrition post-operatively and during and after convalescence These symptoms can be manifested as glossitis stomatitis ulcers of the mucous membranes of mouth cheilosis conjunctivitis photophobia epiphora scleral injection vomiting anorexia diarrhoea neuritis paraesthesias tenderness of calf muscles weakness fatigue vague neuritic pain pellagrous dermatitis burning foot syndrome and bleeding gums etc Basiton Forte Tablets may be prescribed for any of these symptoms

Advantages

- high potency B Complex and vitamin C in Basiton Forte Tablets help overcome even severe physiologic drain
- helps overcome nutritional deficiency

Dosage *For prophylaxis as well as treatment* – one tablet a day is usually sufficient *In severe deficiencies* – one or more tablets a day as decided by the physician

Presentation Basiton Forte Tablets Strips of 10 tablets and boxes of 10 strips of 10 s

Expiration date 18 months

BELAMYL®

Parenteral Solution

B Complex Liver Extract with Vitamin B_{12}

Belamyl supplies B Complex Liver Extract–a source of the whole natural B Complex of Liver with all the anti anaemia factors present Since the effectiveness of crude liver has been repeatedly demonstrated the liver extract in Belamyl is in as crude a form as consistent with safe parenteral administration To the liver extract of Belamyl have been added therapeutic amounts of Vitamin B_{12} – the most potent anti anaemia substance known – and thiamine riboflavine and niacinamide – essential B Complex vitamins

Each 1 ml of Belamyl supplies 0 66 ml Crude Liver Extract equivalent to 1 33 mcg Vitamin B_1 *activity* fortified with

Vitamin B_{12} *Crystalline*	10 mcg
Thiamine Hydrochloride	10 mg
Riboflavine	3 mg
Niacinamide	100 mg

Indications Belamyl is indicated in vitamin B Complex deficiency states and in severe nutritive failure It may also be used therapeutically or adjunctively in beri-beri ariboflavinosis and pellagra both clinical and subclinical It may also be of value in tropical and nutritional macrocytic anaemias the sprue syndrome and in pernicious anaemia

Advantages Four important advantages to the clinician are offered in each single injection of Belamyl

1 A therapeutic dose of the natural B Complex as it occurs in mammalian liver
2 A therapeutic dose of Vitamin B_{12} – one of the most potent anti-anaemia substances known
3 A therapeutic dose of three other critical vitamin B Complex factors
4 Parenteral administration to assure absorption

Administration Belamyl is given by deep intramuscular injection into the upper outer quadrant of the buttock

Dosage Dosage depends on the condition being treated the average dose being 1 ml given 1 to 3 times a week In the treatment of pernicious anaemia particularly in the presence of neurologic symptoms a dose of 1 ml tri weekly is suggested When remission of symptoms occurs a main tenance dose of 1 ml per week may be advisable For the initial treatment of pernicious anaemia Belamyl is to be used in addition to Rubramin® therapy In the presence of neurologic symptoms large supplementary doses of Rubramin or Rubramin H are required

Presentation Vials of 5 ml

Note Belamyl should be kept in a cool place and away from exposure to sunlight

Expiration date 24 months

BREWER S YEAST — Tablets

Brewer s Yeast Tablets are an exceptionally rich source of all the naturally occurring B Complex vitamins These tablets are not artificially fortified

Each 0 35 g Brewer s Yeast Tablet supplies

Thiamine (B_1)	0 035 mg
Riboflavine (B_2)	0 015 mg
Niacin	0 125 mg

In addition each tablet contains the other factors of the B Complex commonly occurring in yeast

Indications Brewer s Yeast Tablets are a useful adjunct to the diets of persons who are not eating the right kind of food every day For persons such as these Brewer s Yeast Tablets can supply significant amounts of the whole natural B Complex

Advantages The yeast in Brewer s Yeast Tablets is especially grown for medicinal use It is not a debittered yeast obtained as a by product of the brewing industry

Brewer s Yeast Tablets are exceptionally palatable because they are flavoured to enhance the nutty taste of the yeast

Dosage To fortify a deficient diet 12 Brewer s Yeast Tablets should be taken daily When the food intake is very limited by serious illness more tablets may be used

Presentation Bottles of 100 and 1 000 tablets

Note Keep in a cool place

Expiration date 24 months

CARBOTUSS® — Tablets

Cold Tablets

Carbotuss Tablets (Cold Tablets) contain an effective combination of well-established drugs for the treatment and symptomatic relief of the common cold

Each Carbotuss Tablet contains

Acetyl p Aminophenol	250 mg
Noscapine	10 mg
Phenylephrine Hydrochloride	5 mg
Carbinoxamine Maleate	1 2 mg
Vitamin C (in the form of Sodium Ascorbate)	20 mg

Action Acetyl-p Aminophenol the active metabolite of acetanilide and acetophenetidin is a non-narcotic non addicting well established analgesic agent Acetyl-p Aminophenol is rapidly absorbed from the gastrointestinal tract of rats and enters into most cells of the body with uniform distribution there is no evidence of appreciable concentrations into any one tissue Acetyl-p Aminophenol does not cause methaemoglobinaemia and it is

rapidly eliminated in the urine in small part in the free form but mainly in conjugation with sulphuric or glucuronic acid

Noscapine is an effective non narcotic non addicting cough suppressant drug and is equal to codeine in its anti tussive effect The exact mechanism by which noscapine suppresses the cough reflex is not known None of the unpleasant side effects of codeine e g constipation miosis blood pressure changes or respiratory depression were observed after noscapine administration Noscapine s action on smooth muscle resembles that of papaverine inducing bronchodilatation with much larger than therapeutic doses Phenylephrine hydrochloride a synthetic sympathomimetic amine closely resembles epinephrine and ephedrine in its pharmacological action particularly in its ability to relieve the nasal congestion of colds and allergy In man phenylephrine hydrochloride causes less nervousness than does ephedrine

Carbinoxamine maleate is an orally effective anti histamine agent that causes minimal side effects in man and animals It is rapidly absorbed from the gastrointestinal tract but its distribution and fate like that of other anti histaminics is not yet known

Ascorbic Acid (Vitamin C) plays an important part in the defence mechanisms of the body Certain authorities reported that a possible relationship exists between the daily intake of ascorbic acid and resistance to infection

Indications Carbotuss Tablets provide anti tussive anti histaminic anti pyretic analgesic and decongestant effects of value in reducing the symptoms of the common cold

Advantages

- Carbotuss provides prompt symptomatic relief in common cold
- suppresses cough as effectively as codeine
- provides useful anti histaminic action with minimal side effects
- strengthens defence mechanism of the body
- Carbotuss is non narcotic
- there is no danger of addiction with Carbotuss
- side effects are negligible

Dosage One or two Carbotuss Tablets should be taken at the first indication of a cold Thereafter one tablet four times daily

Presentation Carbotuss Tablets are supplied in bottles of 20 and 1

CLORUBRA® — Injection

Thiamine Pyridoxine Cyanocobalamin Injection

Clorubra is a combination of Vitamins B_1 B_6 and B_{12} for prevention and treatment of their deficiency states

Each 2 ml of Clorubra contains

Thiamine Hydrochloride		100 mg
Pyridoxine Hydrochloride		50 mg
Cyanocobalamin		1000 mcg
Benzyl alcohol (as preservative) 1 5%	q s	2 ml

Action

Thiamine (Vitamin B_1)

Thiamine plays a vital role in metabolism as prosthetic group for the enzymes involved in decarboxylation of important metabolic intermediates like pyruvic and alpha ketoglutaric acids Thiamine therefore serves an important function in intermediary metabolism Deficiency of this vitamin leads to beri beri The principal symptoms of thiamine deficiency are related to the nervous and the cardiovascular systems and to some extent the gastrointestinal tract Administration of thiamine produces a dramatic response in individuals with beri beri alcoholic neuritis peripheral neuritis of pregnancy and cardiovascular disease and gastrointestinal disorders of nutritional origin

Pyridoxine (Vitamin B_6)

Pyridoxine serves a vital role in metabolism as a coenzyme for a wide variety of metabolic transformations of amino acids Deficiency of pyridoxine produces changes in the skin CNS and the erythropoietic system Seborrhoea like skin lesions about the eyes nose and the mouth glossitis and stomatitis can occur due to pyridoxine deficiency Infantile convulsions and peripheral neuritis are the two manifestations of pyridoxine deficiency on the nervous system Pyridoxine is often given prophylactically and justifiably to patients receiving isoniazid A favourable response to pyridoxine therapy has been elicited when it is used to control the nausea and vomiting of pregnancy (hyperemesis gravidarum) and radiation sickness

In patients with pyridoxine deficiency sideroblastic anaemia is the rule Some cases of sideroblastic anaemias not because of pyridoxine deficiency, also respond to administration of pyridoxine also need parenteral supplementation

Cyanocobalamin (Vitamin B_{12})

The cobalamins appear to be involved directly or indirectly in every known metabolic system in man They are essential for normal growth and nutrition haemopoiesis production of epithelial cells and the maintenance of myelin sheath of the nervous system Deficiency of cyanocobalamin results in the development of pernicious anaemia syndrome Treatment with cyanocobalamin is aimed at replacement of depleted body stores and a constant maintenance of adequate supply Cyanocobalamin is quantitatively and rapidly absorbed when injected intramuscularly or subcutaneously peak levels being reached within an hour after the intramuscular injection The need to inject cyanocobalamin is due to the relatively poor absorption of cyanocobalamin when given by the oral route Thus the high blood levels produced by injection will be effective in replenishing the body stores of vitamin B_{12} in a short duration

For the treatment of pernicious anaemia whether presenting as haematologic or neurologic manifestation or a combination of both cyanocobalamin (Vitamin B_{12}) is recommended by way of injections The need to inject cyanocobalamin occurs when there is an inadequate secretion of intrinsic factor from the stomach This may occur not only in Addisonian pernicious anaemia but also in conditions where gastric mucosa is destroyed such as linitis plastica and neoplasms involving gastric mucosa Gastric atrophy

subtotal and total gastrectomy small bowel fistulas extensive resection of the small intestine Small intestine disruption small bowel lymphoma and Whipple s disease infestation with fish tape worm (Diphyllobothrium latum) the blind loop syndrome megaloblastic anaemia tropical and non tropical sprue etc seen with chronic liver disease and regional ileitis ini tially also produce vitamin B_{12} deficiency necessitating parenteral supple mentation

Although nutritional macrocytic anaemia and megaloblastic anaemia of in- fancy and pregnancy require folic acid for their treatment cyanocobala- min may also be indicated if vitamin B_{12} deficiency is involved

Advantages Clorubra provides prompt vitamin supplementation a wide range of clinical applications rare hypersensitivity reaction and a high concentra tion of vitamin B_{12} It needs no reconstitution or special precautions for preservation

Indications Beri-beri alcoholic neuritis peripheral neuritis of pregnancy cardio vascular disease of nutritional origin gastrointestinal disorders of nutri tional origin and neuralgias such as trigeminal neuralgia and intercostal neuralgia

Seborrhoeic dermatitis epilepsy or peripheral neuritis due to pyridoxine deficiency glossitis stomatitis hyperemesis gravidarum radiation sick ness and patients receiving isoniazid therapy

In megaloblastic anaemias due to deficiency of vitamin B_{12} as seen in infestation with Diphyllobothrium latum small intestinal abnormalities sprue Whipple s disease conditions leading to degeneration of gastric mucosa such as linitis plastica gastric atrophy poisoning due to ingestion of corrosives after gastrectomy degenerative spinal disease and herpes zoster

Contraindications This preparation is contraindicated in patients where paren teral administration of solutions containing thiamine has caused severe allergy or anaphylaxis

Side Effects and Precautions This preparation should be used with caution in persons having a history of significant allergic reactions to thiamine Sensi tivity tests should be performed before administering a therapeutic dose Whenever such reactions occur the drug should be discontinued Admini stration of adrenaline corticosteroids and antihistamines may be given for controlling sensitivity reactions

Administration and Dosage Clorubra should be administered by deep intra muscular injection In severe cases one injection is given daily until the acute symptoms disappear followed by one ampoule 2 3 times a week in milder conditions this dosage may be sufficient from the beginning A maintenance dose of one ampoule once a week to once a month may be required continuously for patients requiring vitamin B_{12}

Presentation Clorubra is available in ampoules each containing 2 ml of solu tion

Note Store in a cool place

Expiration date 2 1 months

CORBETA* Tablets

Propranolol Hydrochloride

Corbeta is Propranolol Hydrochloride a beta adrenergic receptor blocking agent having no agonistic activity It is a competitive reversible antagonist which blocks both beta$_1$ and beta$_2$ receptors It has minimal or no effect when the patient is resting but during physical exercise and moderate stress which involve increased sympathetic activity propranolol has pro found effects due to blockage of beta receptors

Pharmacokinetics Corbeta (Propranolol Hydrochloride) is almost completely absorbed from the gastrointestinal tract Presence of food in the gastro intestinal tract is found to increase the blood level of Corbeta due to decreased inactivation during the first passage through liver More than 90% of Corbeta is bound to plasma proteins and its half life is reported to be approximately 3 5 hours A large amount of Corbeta is inactivated during its first passage through liver hence oral doses of Corbeta are much larger than the parenteral dose Peak plasma concentrations are achieved during 1 1½ hours of oral administration It is rapidly degraded in liver into a number of metabolites out of which 4 hydroxypropranolol is an active metabolite which is responsible for continued beta blocking action up to a period of 6 8 hours

Pharmacodynamics Propranolol (Corbeta) has got the following important actions on various systems of the body

1 It reduces the blood pressure by decreasing cardiac output by decreasing the central sympathetic tone plasma renin activity and resetting the baro receptor mechanism
2 It reduces the oxygen consumption of the heart
3 It exerts an anti arrhythmic effect by preventing the depolarization of the action potentials

Indications

a) Hypertension
Propranolol is indicated in management of cases of mild and moderate benign hypertension When specific contraindications do not exist pro pranolol like thiazide diuretic is considered to be the first drug of choice in initiating the treatment of hypertension

b) Angina Pectoris
Corbeta is indicated in prophylaxis of angina pectoris It improves exer cise tolerance of the patient and reduces the frequency of admini stration of nitrites

c) Hypertrophic Subaortic Stenosis
Corbeta is useful in management of such cases and it reduces exer tional or strees induced angina palpitations and syncope in these patients

d) Cardiac Arrhythmias
Corbeta is indicated in the following cardiac arrhythmias

i) Paroxysmal atrial tachycardia
ii) Atrial arrhythmias induced by catecholamines digitalis or those associated with Wolff Parkinson White Syndrome
iii) Persistent sinus tachycardia
iv) Palpitations and arrhythmias associated with thyrotoxicosis
v) Persistent atrial nodal extrasystoles
vi) In atrial flutter and fibrillation when ventricular rate cannot be con trolled by digitalis or when digitalis is contraindicated
vii) In ventricular tachycardia induced by catecholamines in cardio version techniques

e) Migraine
Corbeta is the first drug of choice in reducing the frequency and inten sity of migraine when used prophylactically on long term basis

f) Pheochromocytoma
Corbeta is useful in management of tachycardia and arrhythmias in patients due to sudden release of catecholamines However it should be used along with an alpha-adrenergic blocker to prevent the other complications of the disease This treatment is also given during pre-operative period in a patient of pheochromocytoma

g) Hyperthyroidism
Corbeta brings about a symptomatic relief of the various manifestations of the disease which are due to increase sensitivity of the heart of catecholamines in presence of thyroid hormone It is also useful in bringing about rapid dramatic improvement in thyroid crisis and can be used prior to surgical thyroidectomy

Corbeta has also been used in various diseases such as schizophrenia anxiety states and tremors etc

Dosage

Hypertension
The treatment is started with a dose of 10 mg twice a day which may be increased until optimal blood pressure response is achieved Effective dose may range from 40 mg to 320 mg/day In some cases the dose of 640 mg/day has also been found to be adquate for smooth control of blood pressure

Angina Pectoris
The treatment is started with 10-20 mg 3 to 4 times a day and may be increased at an interval of 3 7 days until optimal response is obtained Average optimum dose may be 160 mg/day If necessary this can be increased by 320 mg/day

Cardiac Arrhythmias
10 40 mg of propranolol 3 to 4 times a day

Hypertrophic Subaortic Stenosis
20 40 mg of propranolol 3 to 4 times a day

Pheochromocytoma
For preparation of the patient prior to surgery it is used in doses of 60 mg/day in 3 4 divided doses along with alpha-adrenergic blocking agent

Paediatric dose It is not established

Adverse Effects The adverse effects related to cardiovascular system are bradycardia congestive cardiac failure heart block cold extremities atrial insufficiency usually Raynaud s type and paraesthesia The CNS side effects consist of hallucination nightmares weakness of the muscles fatigue sleep disturbances and depression Bronchospasm may occur fever rash thrombocytopenic purpura agranulocytosis have rarely occurred as a hypersensit ve phenomenon Propranolol may cause hypoglycaemia oculomucocutaneous irritation irritation of the serous membrane produ cing fibrosis

Precautions

1 Corbeta should be used cautiously along with certain other drugs such as reserpine guanethidine which cause depletion of catecholamines
2 Patients prone to hypoglycaemia and particularly diabetic patients on treatment with insulin
3 In patients with severe angina when once controlled with large doses of Corbeta the drug should not be withdrawn abruptly because it may lead to severe anginal attack
4 In pregnancy and lactation
5 When the patient is being anaesthetized

Contraindications

1 Bronchial asthma
2 Congestive Cardiac failure
3 Heart block
4 Simultaneous use with verapamil or clonidine

Presentation Corbeta is available in two strengths

Corbeta 40 40 mg scored tablets strips of 10 tablets and boxes of 10 strips of 10 s

Corbeta 10 10 mg scored tablets strips of 10 tablets and boxes of 10 strips of 10 s

CORBETAZINE* — Tablets

Propranolol Hydrochloride (Corbeta*) and
Hydralazine Hydrochloride (Zinepress*)

Corbetazine (40 mg of Propranolol and 25 mg of Hydralazine) is a rational combination of two antihypertensive drugs for management of moderately severe benign hypertension and also for cases of renal hypertension Hydralazine (Zinepress) if used alone in treatment of hypertension may produce undesirable effects such as techycardia increased renin formation and lupus-like syndrome these effects are dose-related The idea of

combining hydralazine with propranolol is to achieve smooth control of blood pressure on a twice a day dosage schedule By giving two drugs together it is possible to reduce the dose of each and also to neutralize the unwanted effects of each other

Pharmacokinetics Corbetazine contains propranolol and hydralazine both of which exhibit markedly similar pharmacokinetic properties Peak plasma concentration of propranolol and hydralazine after administration of Corbe tazine are obtained in 1 to 1½ hours The half-life of both propranolol and hydralazine are nearly similar Acetylation phenotypes are known for hydra lazine Food increases the bioavailability of propranolol as well as hydrala zine

Pharmacodynamics Propranolol has got the following important actions on various systems of the body

1 It reduces the blood pressure by decreasing cardiac output central sympathetic tone plasma renin activity and by resetting the baro receptor machanism

2 It reduces the oxygen requirement of the heart

3 It exerts an antiarrhythmic effect by preventing the depolarization of the action potentials

4 It increases the venous tone by blocking the beta-adrenoceptors allow ing endogenous noradrenaline to act on alpha adrenoceptors

Antihypertensive action of Hydralazine (Zinepress) is due to the direct relax ing effect upon the musculature of precapillary arterioles The fall in blood pressure caused by hydralazine is associated with cardiac stimulation as a reflex response and the cardiac stimulation caused by hydralazine can be blocked by propranolol Adequate doses of hydralazine decreases arterial blood pressure diastolic more than systolic and peripheral vascular resi stance The preferential dilatation of arterioles as compared to veins mini-mizes postural hypotension and promotes the increase in cardiac output It has been noted that the effect of hydralazine may not be parallel to concen-tration in blood Splanchnic coronary cerebral and renal blood flows increase Glomular filtration renal tubular function and urine volume are not consistently affected Hydralazine (Zinepress) usually increases renin secretion but this is antagonized by the betablocking effect of propranolol (Corbeta) on the renal juxtaglomerular cells Thus Corbetazine is a judicious and rational combination of two antihypertensive drugs their antihyperten sive activity is mainly complementary to one another and at the same time diminishing the side effects due to each

Indications

1 Moderate and moderately severe benign essential hypertension

2 Renal hypertension

Dosage The treatment is started with a small dose ½ or 1 tablet of Corbeta zine twice a day and gradually the dose is increased up to 2 tablets twice a day If the blood pressure is not controlled with 2 tablets twice a day the dosage can be increased up to 4 tablets twice a day

Contraindications

1 History of bronchial asthma congestive cardiac failure severe ang nal pain and heart block

2 Simultaneous use of Corbetazine with verapamil or clonidine

Precautions

1 Patients taking reserpine or adrenergic neurone blocking drugs

2 Patients prone to hypoglycaemia

3 Impaired renal or hepatic function

4 Phenotype slow acetylators

5 Corbetazine should not be withdrawn abruptly

Adverse Effects Adverse effects related to cardiovascular systems are brady cardia congestive cardiac failure and heart block The central nervous system side effects may consist of hallucination night mare weakness of muscles fatigue sleep disturbances and depression Bronchospasm may occur Fever rash thrombocytopenic purpura agranulocytosis have rarely occurred as a hypersensitive phenomenon The possibility of lupus like syndrome exists with increased dosage of Corbetazine occasionally head ache may be experienced which tends to disappear on continued therapy

Presentation Corbetazine is supplied as tablets containing 40 mg propranolol hydrochloride and 25 mg hydralazine hydrochloride Strips of 10 tablets and boxes of 10 strips of 10 s

CRYSTICILLIN®

Sterile Powder

Procaine Penicillin G for Aqueous Injection

Crysticillin is available as a sterile powder in vials supplying 3 000 000 units (10 doses) of crystalline procaine penicillin G The product is prepared for injection by adding 8 2 ml aqueous diluent and vigorously shaking the vial to assure a uniform suspension

Indications Specific indications for Crysticillin and suggested dosage regimens are listed in the *Therapy Guide* Penicillin therapy is effective only when the causative organism is penicillin susceptible and the dosage is sufficient to produce bacteriostatic or bactericidal concentrations at the site of infection

Prophylactic use of penicillin is recommended for prevention of possible bacterial endocarditis following tonsillectomy and tooth extraction and other minor surgical procedures in patients with rheumatic heart disease (or history of rheumatic fever) congenital heart disease or other conditions in which secondary infection may occur

Blood Levels Injections of 300 000 units Crysticillin produce a high initial blood level – in most patients a peak of 1 to 1 5 units penicillin/ml serum occurs within 1 or 2 hours Thereafter there is a gradual decline in the blood concentration although demonstrable levels are present in most patients at the end of 24 hours

Blood level data are not conclusive evidence of the therapeutic efficacy of a given dosage regimen The clinical response of the patient and the nature of the disease should determine dosage and frequency of administration

Administration Injection is made rapidly by the intramuscular route following aspiration to be sure the needle is not in a vein The preferred site is the upper outer quadrant of the buttock Injections are easier to make and there is less likelihood of needle blockage if a small bore needle is used use a 20-gauge needle Avoid using a syringe with a loosely fitting plunger as crystals may creep between the walls and cause it to freeze Remove the needle and plunger from the syringe soon after the injection to prevent freezing of the remaining crystals

Dosage

THERAPY GUIDE

Condition	*Daily Dosage Intramuscularly*	*Duration of Treatment*	*COMMENTS*
Infections caused by *Staphylococcus* (susceptible strains) *Streptococcus Pneumococcus*	600 000 u to 1 200 000 u	Continue until temperature is normal for 48 hrs and all manifestations of active infection disappear	In severe infections higher dosage or soluble penicillin at frequent intervals may be required In case of infections due to staphylococci higher dosage may be required and sensitivity tests should be made to determine whether penicillin and/or other antibiotics should be employed Indicated surgical procedures should be carried out in all cases Streptococcal infections should be treated for 10 days in order to guard against the risk of rheumatic fever or glomerulonephritis
Subacute Bacterial Endocarditis If causative organism is sensitive to 0 1 u or less of penicillin per ml	600 000 u or more q 6 h	Continue for a minimum period of 4 to 6 weeks	Perform sensitivity tests before and periodically during treatment Supplemental administration of streptomycin may be advisable If sensitivity of organism exceeds 0 1 u per ml or if response is unsatisfactory administer larger and more frequent doses of penicillin G potassium when infection is under control replace with large doses of aqueous procaine penicillin
Gonorrhoea acute uncomplicated	1 200 000 u to 2 400 000 u for single injection or in two divided doses in two buttocks consecutively at the same sitting		In chronic and complicated cases intensify dosage and prolong treatment until cure is effected Where concomitant syphilis is suspected make darkfield examination before treatment and serologic tests monthly for 3 months

Condition	*Daily Dosage Intramuscularly*	*Duration of Treatment*	*COMMENTS*
Syphilis primary and secondary and latent with negative spinal fluid	600 000 u	Continue for 10 days	
Latent with no spinal fluid examination	600 000 u	Continue for 10 days	The possibility of asymptomatic neurosyphilis must be considered
Late (including symptomatic and asymptomatic neurosyphilis cardiovascular osseous cutaneous and visceral)	600 000 u	Continue until a total of 6 000 000 to 9 000 000 u has been given	Any benefit from more than 10 000 000 units has not been demonstrated
Early congenital (children under 2 years of age)	according to body weight		A total of 100 000 u per kg of body weight should be given in divided doses at 2 to 3 day intervals
Late congenital			Treat as for corresponding stages of acquired syphilis In children under 12 adjust dosage to age and weight Interstitial keratitis usually does *not* respond to penicillin The addition of corticosteroids applied locally to the eyes is recommended
Syphilis in pregnancy			Treatment should correspond to the stage of the disease

The daily dosage for the following infections is Certain strains of Actinomycosis (with sul phonamides) 1 to 5 million units Anthrax 600 000 to 1 2 million units Clostridial infections (with antitoxin) minimum of 20 million units Diphtheria (with antitoxin) up to 2 million units Erysipeloid (swine erysipelas) up to 1 2 million units Ratbite fever (caused by *Spirillum minus*) 1 2 million units Relapsing fever 300 000 to 600 000 units Vincent s infection 300 000 to 600 000 units Treatment should generally continue for at least 48 hours after signs of infection have dis appeared or temperature has returned to normal

For prophylaxis in patients with rheumatic fever or rheumatic or congenital heart disease who are to undergo tonsillectomy tooth extraction or other minor surgery the recommended dosage is either 600 000 units of intramuscular procaine penicillin G daily or 500 000 units of oral potas sium penicillin G four times daily for five days beginning two days before surgery and continuing for two days postoperatively If oral penicillin is used it should be supplemented by 600 000 units intramuscularly on the day of surgery

Precautions There are two active components in Crysticillin penicillin and procaine and it has not been shown that any specific toxicity is produced by their combination as procaine penicillin Any reactions observed can be ascribed to one or the other component

Penicillin There is evidence that toxic reactions to procaine penicillin are some what less common than to penicillin alone Toxic reactions due to penicillin have been largely limited to sensitivity phenomena Such re-actions may include urticaria serum sickness-like reactions (fever rash arthralgia) other skin rashes and rarely anaphylactoid shock They are

more likely to occur in individuals with a history of allergy asthma hay fever or urticaria and in those who have previously demonstrated hypersensitivity to penicillin Urticarial serum sickness like and other skin rash reactions may be controlled by antihistamines and if necessary corticosteroids Whenever such reactions occur penicillin should be discontinued unless in the opinion of the physician the condition being treated is life-threatening and amenable only to penicillin therapy Serious anaphylactoid reactions are not controlled by antihistamines and require such measures as the immediate use of epinephrine oxygen intravenous corticosteroids and fluids if hypotension is intractable

Evidence of the possible overgrowth of non susceptible organisms should be looked for when any penicillin is administered

Procaine The most common toxic reaction to procaine – neurologic changes such as excitement apprehension twitching and convulsions – is caused by overdosage But the small amount of procaine in Crysticillin makes the possiblity of such reactions remote except in procaine idiosyncrasy or hypersensitivity Oxygen and intravenous barbiturates are indicated should such changes occur

In rare cases procaine sensitivity may produce a circulatory reaction with pallor tachycardia chest pain diplopia and blurring of vision or sudden collapse characterized by circulatory failure Administer artificial respiration and oxygen immediately in this type of reaction intravenous barbiturates are ineffective

Preliminary intradermal skin test to detect penicillin sensitivity should be performed routinely to avoid severe anaphylactic reaction Intradermal test may also give rise to anaphylactic reaction in sensitive individuals hence measures to combat such reaction should be available

Where procaine sensitivity is suspected perform a preliminary intradermal skin test If the test is positive do not administer procaine penicillin

Presentation Vials of 3 000 000 units (10 doses) boxes of 10 vials

Expiration date 24 months at room temperature in the dry state Sterile suspensions may be kept for 1 week at room temperature and for 21 days if refrigerated *Shake vial well before use*

CRYS-4® CRYS-8® and CRYS-12® — Sterile Powder

Procaine Penicillin G Fortified with
Buffered Crystalline Sodium Penicillin G for Aqueous Injection

CRYS-4 is the fortified aqueous procaine penicillin which comes in 3 strengths for the routine use in susceptible infections and for more severe infections and highly resistant infections

	Crystalline Sodium Penicillin G	*Procaine Penicillin G*	*Required amount of diluent*	*Total volume of Injection*
CRYS-4	100 000 units	300 000 units	0 9 ml	1 1 ml
CRYS-4 (5 dose)	500 000 units	1 500 000 units	4 0 ml	5 1 ml
CRYS-8	200 000 units	600 000 units	0 6 ml	1 1 ml
CRYS 12	300 000 units	900 000 units	1 0 ml	1 9 ml

Action With all three preparations the initial penicillin blood level is high and a satisfactory level is maintained for protracted periods The difference is in the degree of height and duration which are adopted to the treatment of infections that are more or less severe and have varying degrees of bac terial resistance

Indications Specific indications and suggested dosage regimens are given in *Therapy Guide* CRYS-4 is recommended for the prophylaxis and treatment of infections susceptible to penicillin Penicillin therapy is effective only when the causative organism is penicillin susceptible and the dosage is sufficient to produce bacteriostatic or bactericidal concentrations at the site of infection or a period long enough to allow body defences to eradi cate the infection

Prophylactic use of penicillin is recommended for prevention of possible bacterial endocarditis following tonsillectomy tooth extraction and other minor surgical procedures in patients with rheumatic heart disease (or history of rheumatic fever) congenital heart disease or other conditions in which secondary infection may occur

Blood Levels Injections of 1 ml CRYS 4 (300 000 units procaine penicillin G and 100 000 units sodium penicillin G) produce n most patients a peak blood level of 2 units or more penicillin/ml serum within 1 or 2 hours Therefore the preparation is particularly advantageous when high penicillin blood levels are needed promptly After the initial peak there is a gradual decline in the blood concentration although demonstrable levels are pre sent in most patients at the end of 24 hours The prolonged effect is shortened in ambulatory patients

Blood level data are not conclusive evidence of the therapeutic efficacy of a given dosage regimen The clinical response of the patient and the nature of the disease should determine dosage and frequency of administration

Administration CRYS 4 is administered by deep intramuscular injection the preferred site is the upper outer quadrant of the buttock

Dosage One daily dose of CRYS-4 is usually sufficient for prophylaxis or for the treatment of mild infection Larger and/or more frequent doses should be employed in proportion to the severity of the infection In such cases single injections of CRYS-8 or CRYS-12 may be given

THERAPY GUIDE

Condition	*Daily Dosage Intramuscularly*	*Duration of Treatment*	*COMMENTS*
Infections caused by *Staphylococcus* (susceptible strains) *Streptococcus Pneumococcus*	400 000 u	Continue until temperature is normal for 48 hrs and all manifestations of active infection disappear	In severe infections higher dosage or soluble penicillin at frequent intervals may be required In case of infections due to staphylococci higher dosage may be required and sensitivity tests should be made to determine whether penicillin and/or other antibiotics should be employed Indicated surgical procedures should be carried out in all cases Streptococcal infections should be treated for 10 days in order to guard against the risk of rheumatic fever or glomerulonephritis
Subacute Bacterial Endocarditis If causative organism is sensitive to 0 1 unit or less of penicillin per ml	800 000 u or more q 6 h	Continue for a minimum period of 4 to 6 weeks	Perform sensitivity tests before and periodically during treatment Supplemental administration of streptomycin may be advisable If sensitivity of organism exceeds 0 1 u per ml or if response is unsatisfactory administer larger and more frequent doses of potassium penicillin G When infection is under control replace with large doses of aqueous procaine penicillin
Gonorrhoea acute uncomplicated	1 200 000 u to 2 400 000 u in a single dose or in two divided doses at the same sitting		In chronic and complicated cases intensify dosage and prolong treatment until cure is effected Where concomitant syphilis is suspected make darkfield examination before treatment and serologic tests monthly for 3 months
Syphilis Primary and secondary and latent with negative spinal fluid	800 000 u	Continue for 10 days	
Latent with no spinal fluid examination	800 000 u	Continue for 10 days	The possibility of asymptomatic neurosyphilis must be considered

Condition	*Daily Dosage Intramuscularly*	*Duration of Treatment*	*COMMENTS*
Late (including symptomatic and asymptomatic neurosyphilis cardiovascular osseous cutaneous and visceral)	800 000 u	Continue until a total of 8 000 000 to 10 000 000 u has been given	Any benefit from more than 10 000 000 units has not been demonstrated
Early congenital (children under 2 years of age)	according to body weight		A total of 100 000 u per kg of body weight should be given in divided doses at 2 to 3 days intervals
Late congenital			Treat as for corresponding stages of acquired syphilis In children under 12 adjust dosage to age and weight Interstitial keratitis usually does not respond to penicillin The addition of corticosteroids applied locally to the eyes is recommended
Syphilis in pregnancy			Treatment should correspond to the stage of the disease

The daily dosage for the following infections is Certain strains of Actinomycosis (with sul phonamides) 1 to 5 million units Anthrax 800 000 to 1 2 million units Clostridial infections (with antitoxin) minimum of 20 million units Diphtheria (with antitoxin) up to 2 million units Erysipeloid (swine erysipelas) up to 1 2 million units Ratbite fever (caused by *Spirillum minus*) 1 2 million units Relapsing fever 400 000 to 800 000 units Vincent s infection 400 000 to 800 000 units Treatment should generally continue for at least 48 hours after signs of infection have disappeared or temperature has returned to normal

For prophylaxis in patients with rheumatic fever or rheumatic or congenital heart disease who are to undergo tonsillectomy tooth extraction or other minor surgery the recommended dosage is either 800 000 units of intramuscular penicillin daily or 500 000 units of oral potassium penicillin G four times daily for five days beginning two days before surgery and continuing for two days postoperatively If oral penicillin is used it should be supplemented by 800 000 units intra mascularly on the day of surgery

Precautions There are two active components in CRYS-4 penicillin and pro caine and it has not been shown that any specific toxicity is produced by their combination as procaine penicillin Any reactions observed can be ascribed to one or the other component

Penicillin Toxic reactions due to penicillin have been largely limited to sensitivity phenomena Such reactions may include urticaria serum sick ness like reactions (fever rash arthralgia) other skin rashes and rarely anaphylactoid shock They are more likely to occur in individuals with a history of allergy asthma hay fever or urticaria and in those who have previously demonstrated hypersensitivity to penicillin Urticarial serum sickness like and other skin rash reactions may be controlled by anti histamines and if necessary corticosteroids Whenever such reactions occur penicillin should be discontinued unless in the opinion of the physi cian the condition being treated is life threatening and amenable only to

penicillin therapy Serious anaphylactoid reactions are not controlled by antihistamines and require such measures as the immediate use of epine phrine oxygen and intravenous corticosteroids

Evidence of the possible overgrowth of non susceptible organisms should be looked for when any penicillin is administered

Preliminary intradermal skin test to detect penicillin sensitivity should be performed routinely to avoid severe anaphylactic reaction Intradermal test may also give rise to anaphylactic reaction in sensitive individuals hence measures to combat such reaction should be available

Procaine The most common toxic reaction to procaine – neurologic changes such as excitement apprehension twitching and convulsions – is caused by overdosage But the small amount of procaine in CRYS 4 makes the possibility of such reactions remote except in procaine idiosyncrasy or hypersensitivity Oxygen and intravenous barbiturates are indicated should such changes occur

In rare cases procaine sensitivity may produce a circulatory reaction with pallor tachycardia chest pain diplopia and blurring of vision or sudden collapse characterized by circulatory failure Administer artificial respiration and oxygen immediately in this type of reaction intravenous barbiturates are ineffective Where procaine sensitivity is suspected perform a pre liminary intradermal skin test If the test is positive do not administer procaine penicillin

Presentation CRYS 4 Vials of 400 000 units boxes of 25 vials and vials of 2 000 000 units (5 doses) boxes of 10 vials
CRYS-8 Vials of 800 000 units boxes of 10 vials
CRYS 12 Vials of 1 200 000 units boxes of 10 vials

Expiration date 24 months May be stored at room temperature Sterile suspension may be kept for 1 week without significant loss of potency if refrigerated

DI-ADEMIL® — Tablets

Hydroflumethiazide

Di-Ademil is a potent oral diuretic indicated in the control of oedema of varied aetiologies and in hypertension Chemically Di-Ademil (Hydroflu-methiazide) is designated as 3 4 dihydro-6-(trifluoromethyl) 1 2 4-benzo thiadiazine-7 sulphonamide 1 1-dioxide and is related to chlorothiazide It is one of a series of diuretics containing a trifluoromethyl group a modifica tion which appears to result in outstanding diuretic and antihypertensive action of extended duration with minimal adverse effects on plasma electro lyte levels

Action Pharmacologic and clinical studies have demonstrated that Di-Ademil is a potent oral diuretic Clinical comparison studies have shown that it produces an equivalent diuresis with about one tenth the dosage required for chlorothiazide When given in a dose one tenth that of chlorothiazide Di-Ademil exhibits the same antihypertensive properties but produces some what greater water and sodium output with less potassium and bicarbonate

loss Di Ademil therapy is outstandingly effective not only in establishing but in maintaining excretion of retained fluid in oedematous patients More over the duration of action of hydroflumethiazide is sufficiently prolonged to allow a single daily administration in most patients

Di-Ademil has both diuretic and antihypertensive action It does not cause hypotension in normotensive individuals Used alone or in conjunction with other antihypertensive agents Di Ademil permits great flexibility in the management of hypertension When Di-Ademil is given alone to patients with mild hypertension it may induce a significant lowering of the blood pressure within a week and frequently to within the normal range by the end of the third week of therapy When added to an established anti hypertensive drug regimen Di Ademil may produce a further lowering of blood pressure

Di Ademil is especially useful when long-term therapy is required since the beneficial effects of Di Ademil do not diminish with continuous daily administration The optimal saluretic action of Di-Ademil obviates the need for drastic restriction of salt intake The onset of diuretic action of Di Ademil is rapid (within 3 hours) nevertheless the action is gentle and sustained (evenly distributed over 8 to 12 hours)

Indications Di-Ademil is indicated in the management of oedema and whenever diuresis is required Specifically this potent diuretic is useful in the treatment of oedema in congestive heart failure oedema of the pre-menstrual syn drome oedema of nephrosis and nephritis oedema and ascites due to cirrhosis of liver and oedema induced by the use of drugs such as certain steroids Clinical experience has shown that patients with allergic responses to chlorothiazide or those who have developed tolerance to the drug can be successfully transferred to Di-Ademil

Dosage The dosage should be individualized and adapted to the condition

Oedema To initiate therapy the suggested daily dose of Di-Ademil is 100 mg given in divided doses preferably morning and early afternoon maintenance dosage may vary from 25 mg to 100 mg daily in divided doses morning and afternoon

Hypertension The suggested initial dose of Di Ademil is 50 to 100 mg daily given in divided doses The maintenance dosage may range from 25 to 50 mg once or twice a day depending on the response of the patient

Precautions No serious side effects attributable to Di Ademil have been reported in clinical experience to date A few cases of mild pruritus and minor gastro intestinal disturbances have been reported As with the use of any potent diuretic of this type hypochloraemic alkalosis with or without hypokalae mia may occur in some individuals Generally a high dietary intake of potassium as afforded by citrus fruit juices as well as a balanced diet of meat and vegetables helps to preclude the occurrence of these unwanted effects Cirrhotic patients have been reported to show a particular prone ness to the development of hypokalaemia For this reason cirrhotic patients or those whose sodium intake is rigidly restricted should be observed closely and at regular intervals for early signs of fluid and/or electrolyte disturbances so that appropriate corrective measures can be taken promptly

Patients receiving digitalis therapy should also be carefully watched for hypokalaemia Development of hypokalaemia due to diuretic therapy may precipitate or potentiate digitalis toxicity

Supplemental oral potassium therapy may be given to patients likely to develop hypokalaemia

Care should be exercised in administering a potent diuretic agent to patients with severely damaged kidneys or to those with renal insufficiency and increasing azotaemia In the presence of complete renal shutdown therapy with any diuretic agent (including Di Ademil) is contraindicated

Therapy with benzothiadiazine derivatives may result in increased glycaemia or glycosuria in diabetic patients and may unmask a diabetic predisposition in apparently normal individuals

Increased serum uric acid concentrations have occurred occasionally and a few instances of leg or abdominal cramps and a few cases of pruritus rash or other dermatologic manifestations have also been reported Gastro intestinal disturbances (nausea vomiting or abdominal pain) may be en countered in some patients As with any new drug entity such complications as neutropenia or purpura with or without thrombocytopenia and unusual manifestations suggestive of unusual sensitivity should be kept in mind

Presentation Bottles of 20 and 100 tablets each containing 25 mg of hydro flumethiazide May be stored at room temperature

DICRYSTICIN-S® **Sterile Powder**

DICRYSTICIN-S® 800 **Sterile Powder**

DICRYSTICIN-S® FORTIS **Sterile Powder**

Streptomycin with Sodium and Procaine Penicillin G

Dicrysticin S is supplied as a dry powder in 1 dose vials Each dose of Dicrysticin S provides 300 000 units procaine penicillin G 100 000 units buffered crystalline sodium penicillin G and 0 5 g pure streptomycin base in the form of streptomycin sulphate The preparation also contains sodium citrate as a buffer

Dicrysticin-S 800 is supplied as a dry powder in 1 dose vials Each dose of Dicrysticin S 800 provides 600 000 units procaine penicillin G 200 000 units buffered crystalline sodium penicillin G and 0 5 g of pure streptomycin base in the form of streptomycin sulphate The preparation also contains sodium citrate as a buffer

Dicrysticin S Fortis is supplied as a dry powder in 1 dose vials Each dose of Dicrysticin S Fortis provides 300 000 units procaine penicillin G 100 000 units sodium penicillin G and 1 0 g pure streptomycin base in the form of streptomycin sulphate The preparation also contains sodium citrate as a buffer

Advantages

- of particular value in treating some mixed infections
- may be given in surgery where there is danger of contamination particularly from the contents of a hollow viscous

Indications Dicrysticin S Dicrysticin-S 800 and Dicrysticin-S Fortis are recommended in the treatment of peritonitis mediastinitis suspected brain abscess and other infections in which the causative organisms cannot be identified without unwarranted operative procedures Whenever possible however a thorough search for the primary focus should be made in order to determine if sensitivity to these combinations warrants their use They are also recommended in some mixed infections particularly those involving both gram positive and gram-negative organisms e g those common in the respiratory or urogenital tract and in contaminated wounds Dicrysticin-S Dicrysticin-S 800 and Dicrysticin-S Fortis may be given in surgery where there is danger of contamination particularly from the contents of a hollow viscous When treatment is prolonged as for subacute bacterial endocarditis it is wise to perform periodic *in vitro* sensitivity tests to determine any change in the sensitivity of the causative organism

Note Combination products with streptomycin and penicillin in the pro portions provided by these preparations are not devised to meet paediatric needs If the physician deems the concomitant administration of penicillin and streptomycin advisable in infants and children dosage must be deter mined by the streptomycin content because of toxicity (For details see Dicrysticin S Pediatric)

Dosage The dose of Dicrysticin-S Dicrysticin-S 800 or Dicrysticin-S Fortis should be determined primarily by the current recommended dosage of streptomycin In surgical prophylaxis 1 dose of Dicrysticin-S or Dicrysticin S 800 is injected every 8 or 12 hours beginning 1 or 2 days before surgery and continuing for 7 to 10 days post-operatively The recommended dosage of Dicrysticin-S Fortis is 1 dose every 12 or 24 hours beginning 1 or 2 days before surgery and continuing for 7 to 10 days post-operatively When larger amounts of Dicrysticin S Dicrysticin S 800 or Dicrysticin S Fortis are required as in septicaemia or peritonitis the total daily dose should provide no more than 2 g of streptomycin in the treatment of such infections as peritonitis supplementary penicillin therapy may be advisable in case a larger amount is needed

Probably the best guide to the duration of treatment is provided by the clinical response of the patient It is recommended that treatment be continued for 3 or 4 days after the temperature has returned to normal or cultures have become consistently negative

Administration

1 Suspend these preparations in sterile distilled water or sterile isotonic solution in the following manner

Dicrysticin-S To provide a volume of 2 ml per dose add 1 5 ml diluent to the 1 dose vial and 7 0 ml to the 5 dose vial

Dicrysticin-S 800 To provide a volume of 2 ml per dose add 1 6 ml diluent to the 1 dose vial

Dicrysticin-S Fortis To provide a volume of 3 ml per dose add 2 5 ml diluent to the 1 dose vial

Direct the stream of diluent against the bottom of the vial

Shake vigorously until all the diluent has been added and the suspension is smooth and uniform

2 Inject air into the vial for easier withdrawal

3 Have the suspension at room temperature before administration

4 After withdrawing the dose into the syringe make sure that the needle is empty by pulling the plunger back until a small air bubble appears

5 Inject the suspension *intramuscularly* The likelihood of painful injection is reduced if the following precautions are observed Inject high in the upper outer quadrant of the buttock Change the site for each injection Insert needle deeply to avoid subcutaneous deposition Inject slowly

Dicrysticin S Dicrysticin S 800 and Dicrysticin S Fortis should never be given intravenously

Avoid a loosely fitting plunger in the syringe Procaine penicillin crystals may creep between the walls and cause it to freeze Remove the needle and plunger from the syringe soon after the injection to prevent freezing of remaining crystals Wash before resterilization

Precautions There are three active components in these formulations Procaine , penicillin and streptomycin It has not been shown that any specific toxicity results from the chemical combination of procaine with penicillin or the simultaneous administration of streptomycin However any unusual reactions should receive immediate medical attention

Penicillin Toxic reactions to penicillin are largely limited to hypersensitivity phenomena The manifestations of hypersensitivity range from a mild erythema or urticaria to severe serum sickness and rarely anaphylactoid shock Before these preparations are administered the patient should be questioned as to previous evidence of sensitivity to penicillin or a history of bronchial asthma or allergy all of which increase the likelihood of hypersensitivity If a hypersensitivity reaction occurs that is more serious than the condition being treated and it cannot be controlled this medication should be discontinued For the rare occurrence of anaphylactoid shock the physician should be prepared to institute remedial measures immediately such as the administration of oxygen vasopressor agents and intravenous steroids

Preliminary intradermal skin test to detect penicillin sensitivity should be performed routinely to avoid severe anaphylactic reaction Intradermal test may also give rise to anaphylactic reaction in sensitive individuals hence measures to combat such reaction should be available

Procaine The most common toxic reactions to procaine – neurologic changes such as excitement apprehension twitching and convulsions are caused by overdosage The small amount of procaine in these preparations makes the possibility of such reactions remote Oxygen and intravenous barbiturates are indicated should such neurologic changes occur

In rare cases procaine sensitivity may produce a circulatory reaction with pallor tachycardia chest pain diplopia and blurring of vision or sudden collapse characterized by circulatory failure Administer artificial respiration and oxygen immediately in this type of reaction intravenous barbiturates are ineffectiv

Where proce sensitivity is suspected perform a preliminary intradermal test If the te positive do not administer Dicrysticin-S or Dicrysticin S 800 or Dic n-S Fortis

Streptomycii eptomycin in sufficiently large doses may produce vesti bular or audi amage of which vertigo and tinnitus are the most com mon sympto uch toxicity most often occurs after prolonged dosage Streptomycir ss apt to produce auditory damage than is dihydro streptomycir mparable dosage However streptomycin is more apt to produce ves r damage Auditory impairment is usually permanent vestibular da may be permanent but symptoms tend to disappear as the patient adjusts and learns to compensate visually Ability to compen sate for vestibular impairment decreases with age Streptomycin prepara tions therefore should be used with caution in elderly patients

The caloric stimulation test for vestibular function and audiometric tests are advisable during prolonged streptomycin therapy to detect signs of developing eighth nerve damage test should be made before treatment is started and periodically thereafter

The blood concentration of streptomycin should not exceed 20 to 25 mcg/ml plasma Pre existing renal impairment interferes with streptomycin excretion producing high blood levels and increasing the risk of vestibular and auditory dysfunction

Skin or allergic reactions occur infrequently and can usually be controlled with antihistaminic agents

Signs of kidney involvement (proteinuria haematuria and occasional azotaemia) generally disappear on withdrawal of the drug Unless renal function is impaired changes in the urine are usually not cause for inter-rupting therapy

Headache paraesthesias of the face and gastric disturbances may occur Clinical judgement as to termination of therapy must be exercised when such side effects occur

Evidence for the possible overgrowth of non susceptible organisms must be looked for when antibiotics are administered

Presentation Dicrysticin-S Vials of 1 dose and 5 doses boxes of 25 vials Dicrysticin S 800 and Dicrysticin-S Fortis Vials of 1 dose boxes of 25 vials

Expiration date for all these preparations 24 months at room temperature Sterile suspensions may be kept in the refrigerator for 1 week without significant loss of potency

DICRYSTICIN-S® PEDIATRIC — Sterile Powder

Streptomycin with Sodium and Procaine Penicillin G

Dicrysticin S Pediatric is supplied as a dry powder in one dose vials Each dose of Dicrysticin-S Pediatric provides 300 000 units procaine penicillin G 100 000 units buffered crystalline sodium penicillin G and 0 25 g of pure streptomycin base in the form of streptomycin sulphate

Dicrysticin S Pediatric is indicated for prophylaxis before and after surgery in or near a contaminated site for the treatment of certain mixed infections caused by both gram positive and gram negative organisms particularly chronic infections of the respiratory or urogenital tract for the treatment of infections in which the causative organism cannot be readily identified especially peritonitis mediastinitis or brain abscess (in such cases how ever whenever possible a thorough search for the primary focus should be made in order to determine if sensitivity to this antibiotic combination warrants its use) and for the treatment of selected cases of septicaemia or subacute bacterial endocarditis in which there is *in vitro* evidence that the combination of penicillin and streptomycin has an additive or synergistic effect When treatment is prolonged as for subacute bacterial endocardi tis it is wise to perform periodic sensitivity tests to determine any change in the sensitivity of the causative organism Dicrysticin-S Pediatric may be effective in infections where the bacteria are relatively more resistant to penicillin or streptomycin drugs alone than to the combination

Dosage The dose of Dicrysticin S Pediatric should be determined primarily by the currently recommended dosage of streptomycin The best guide to the duration of treatment is provided by the clinical response of the patient The following schedule is recommended

	* *Daily Dose*
Under 1 year	0 8 ml (½ vial)
Under 3 years	1 65 ml (1 vial)
Under 6 years	1 65 to 3 3 ml (1 to 2 vials)
More than 6 years	3 3 ml (2 vials)

* Either as a single dose or 2 equally divided doses per day In more severe infections the dosage may be doubled

Administration One of the outstanding features of Dicrysticin S Pediatric is ease of administration For reconstitution Dicrysticin S Pediatric may be suspended in sterile distilled water or sterile isotonic sodium chloride To provide a volume approximately of 1 65 ml per dose of Dicrysticin-S Pediatric add 1 2 ml diluent to the vial The administration is a matter of simple *intramuscular* injection after aspirating to be sure that the needle is not in a vein

Note This product should never be given intravenously

Dicrysticin S Pediatric in powder form is stable at room temperature Sterile suspension may be kept in the refrigerator for 1 week without significant loss of potency

Presentation Vials of 1 dose (1 2 ml diluent to be added) boxes of 25 vials

Expiration date 24 months May be stored at room temperature

DI-RAUDIXIN® Tablets

DI-RAUDIXIN® FORTE Tablets

Standardized Whole Root Rauwolfia Serpentina (Raudixin®) and Hydroflumethiazide (Di Ademil®)

Di Raudixin conveniently combines the antihypertensive tranquillizer Raudixin (Standardized Whole Root Rauwolfia Serpentina) and the anti hypertensive diuretic Di-Ademil (Hydroflumethiazide) in a single tablet The resulting antihypertensive effect is potentiated being greater than that obtained with either component alone As a result Di-Raudixin provides effective therapy for moderate degree of hypertension It lowers blood pressure safely and dependably – there are no extremes or sudden drops in pressure when the patient is on Di-Raudixin Di Raudixin is available in two potencies Di Raudixin – 50 mg Raudixin and 25 mg Di Ademil and Di Raudixin Forte – 50 mg Raudixin and 50 mg Di Ademil

Action The action of Di Raudixin is essentially due to its two components i e Raudixin and Di-Ademil

Whole root *Rauwolfia Serpentina* (Raudixin) one of the two basic compo nents of Di Raudixin is a time tested antihypertensive agent whose value has been confirmed by the evidence of many years of growing clinical use Raudixin being *standardized* whole root has a greater and more balanced therapeutic action than can be produced by any single Rauwolfia alkaloid It has three basic pharmacologic effects It lowers systolic and diastolic blood pressure provides tranquillization and induces a mild reduction in pulse rate Reduction in blood pressure is both gradual and sustained thus protecting the patient against sharp fluctuations Normotensive individuals are not significantly affected Raudixin s mild sedative action tends to depress the aggravating effects of emotional tension and upsets This tranquillizing effect is also valuable in helping to alleviate other common hypertensive symptoms such as irritability headache anxiety insomnia and palpitations Patients generally experience a feeling of well being emotional difficulties occur less frequently there is less likelihood of depres sion The mild bradycardia lowers the work load of the heart helping to increase cardiac efficiency Raudixin potentiates other antihyperten sive agents – when used in combination lesser amounts of the more potent and toxic drugs can be used

Raudixin is clinically reliable and effective on continued administration It causes no liver dysfunction Tolerance and cumulation have not been reported

The Di Ademil component is a benzothiadiazine derivative an effective anti hypertensive diuretic Its structural formula is 3 4-dihydro-6 (trifluoro methyl)-1 2 4-benzothiadiazine-7-sulphonamide 1 1-dioxide Clinical studies have shown that 100 mg Di-Ademil has therapeutic effect equiva lent to 1000 mg of the chemically related chlorothiazide Potassium excretion is notably less with Di-Ademil Di-Ademil lowers blood pressure smoothly and significantly and is useful in moderate degree of hyperten sion whether alone or in combination with other potent antihypertensive agents

The antihypertensive actions of Raudixin and Di-Ademil are complementary and the combination of both in Di-Raudixin and Di-Raudixin Forte elicit more favourable therapeutic response than could be expected with either one of its components

These preparations complement the hypotensive action of ganglionic blocking agents or hydralazine permitting and even necessitating considerably small doses of these more toxic drugs and thereby decreasing the incidence and severity of their side effects

Advantages Di-Raudixin and Di-Raudixin Forte provide numerous and significant beneficial effects in the management of moderate degree of hypertension

Di-Raudixin and Di Raudixin Forte offer –

all the advantages of Raudixin

- standardized whole root Rauwolfia serpentina
- gentle gradual antihypertensive action – the Rauwolfia preparation of choice
- tranquillization to help relieve common emotional aspects of hypertension such as anxiety tension headache insomnia and palpitations
- mild bradycardia to lower the work load of the heart and help increase cardiac efficiency
- non-habituation
- fewer gastrointestinal side effects
- long-term safety (has been given continuously for years)

plus
all the advantages of hydroflumethiazide

- unsurpassed diuretic action for prompt attainment of an oedema-free state
- effective sustained antihypertensive action
- virtual absence of drug tolerance
- minimal effects on electrolyte balance and blood chemistry
- reduced need for salt restriction
- low incidence of side effects

plus

- increased efficacy sufficient for moderate degree of essential hypertension
- complementary antihypertensive action permitting smaller doses of both components
- complementary antihypertensive effect permitting and necessitating reduced dosage by as much as one-half of other antihypertensive drugs such as ganglionic blocking agents or hydralazine
- gentle gradual sustained reduction of systolic and diastolic blood pressure more efficient control of hypertension on a convenient simplified dosage schedule
- particularly effective in hypertensive cardiovascular conditions manifesting oedema
- well-tolerated over extended periods of administration
- no contraindications except in the presence of complete renal shutdown

Indications Di Raudixin and Di-Raudixin Forte are effective in moderate degree of hypertension Their gentle safe wide range antihypertensive action is particularly useful when blood pressure reduction is required when there are signs of congestive failure or oedema when there is insufficient re sponse to a single antihypertensive agent when partial or complete re placement of potentially more toxic antihypertensive drugs is desirable

Di-Raudixin and Di Raudixin Forte are sufficient for hypertensive patients When an additional antihypertensive effect is needed however more drastic antihypertensive agents may be used concomitantly Both afford smoother control of blood pressure and permit and even necessitate consi derable lower dosage of these more toxic hypotensive agents After an ade quate response is obtained and maintenance dosages established it may gradually be possible to eliminate the other agents and maintain the patient on Di Raudixin or Di Raudixin Forte

Both Di Raudixin and Di-Raudixin Forte are indicated for moderate degree of hypertension Di-Raudixin however may be of greatest value for long term maintenance therapy of hypertension when associated oedema has been satisfactorily relieved or a higher ratio of the Raudixin component to the Di-Ademil component is needed

Dosage Dosage should be adjusted to individual requirements

DOSAGE SUMMARY

Dosage Strength	*Indication*	*Daily Regimen*
Di Raudixin 50 mg Raudixin 25 mg Di Ademil	Moderate degree of hypertension but where a lower dose of the diuretic is desired	1 to 3 tablets daily depending on the patient response
Di Raudixin Forte 50 mg Raudixin 50 mg Di Ademil	Moderate degree of hypertension espe cially when the patient is markedly oedematous	Initial dosage range 1 to 3 tablets preferably in divided doses morning and afternoon Maintenance – as low as 1 tablet daily may suffice

Precautions Raudixin is remarkably well tolerated over extended periods of administration Since the combined use of Raudixin and Di-Ademil makes possible lower doses of rauwolfia the likelihood of any unwanted effects is diminished Rauwolfia side effects such as diarrhoea weight gain nausea and vomiting drowsiness nasal congestion increased dreaming and reversible extrapyramidal symptoms are less likely to occur with the Di-Raudixin regimen

No serious side effects attributable to Di Ademil have been reported in clinical trials to date A few cases of mild pruritus and minor gastrointesti- nal disturbances have been reported As with any potent diuretic of this

type however a rare hypochloraemic alkalosis with or without hypokalaemia may occur Generally a high potassium intake as supplied by orange or tomato juice and a balanced diet of meat and vegetables helps preclude these unwanted effects Hypokalaemia may need supplemental potassium

Care should be taken in treating patients with severely damaged kidneys and low urine output

Note There are no absolute contraindications to the use of Di-Raudixin except complete renal shutdown However any preparation containing rauwolfia should be used with caution in patients with a history of depression peptic ulcer or ulcerative colitis

Presentation Di-Raudixin (both potencies) is supplied as capsule shaped tablets in bottles of 20 and 100

ENGRAN® Tablets

Vitamin-Mineral Supplement

Whenever vitamin-mineral supplementation is required just 1 Engran Tablet daily provides high supplemental dosages of the essential vitamins to help meet increased nutritional requirements In each small tablet Engran supplies high supplemental dosages of the essential vitamins supplemental calcium in phosphorus-free form supplemental iron plus trace elements

Each Engran Tablet supplies

VITAMINS	
Vitamin A	5 000 I U
Vitamin D	500 I U
Vitamin B_1	3 mg
Vitamin B_2	3 mg
Vitamin B_6	2 mg
Vitamin B_{12}	2 mcg
Folic Acid	1 mg
Niacinamide	20 mg
Calcium Pantothenate	5 mg
Vitamin C	75 mg
Vitamin K	0 5 mg
MINERALS	
Calcium	0 15 g
Iodine	0 15 mg
Iron	10 mg
Potassium	5 mg
Copper	1 mg
Manganese	1 mg
Magnesium	6 mg
Zinc	1 5 mg

Indications Engran is indicated as a dietary supplement during pregnancy lactation or whenever routine vitamin-mineral supplementation is required

Dosage One Engran Tablet daily or as indicated

Presentation Capsule shaped tablets in bottles of 25 and 100

Note Keep tightly closed in a cool and dark place

Expiration date 18 months

ETINOL† — Tablets

Ethambutol Hydrochloride

Etinol (Ethambutol Hydrochloride) is an oral chemotherapeutic agent specifically effective against Mycobacterium tuberculosis Chemically Etinol is d ethylene diamino-di-butanol dihydrochloride

Pharmacokinetics About 75 80% of an orally administered dose is absorbed from gastrointestinal tract Following a single dose of 25 mg/kg of body weight the concentration in the plasma achieved is 5 mcg/ml within 2 4 hours The drug has a half-life of 3 4 hours About 50% of the peak concentration is present in blood at 8 hours and less than 10% at 24 hours The concentration of Etinol in erythrocyte is about twice that in plasma and thus red blood cells may serve as a depot from which the drug slowly enters the plasma Within 24 hours 50% of the ingested dose is excreted unchanged in the urine The drug is excreted both by tubular secretion as well as glomeruler filtration Food does not interfere with absorption of ethambutol

Pharmacodynamics Nearly all strains of *M tuberculosis* and *M kansasii* are sensitive to ethambutol in concentration of 8 mcg/ml or less Ethambutol has no effect on other bacteria It suppresses the growth of isoniazid and streptomycin resistant tubercle bacilli Resistance to ethambutol develops very slowly and with difficulty *in vitro*

Ethambutol is tuberculostatic drug Mycobacteria take up ethambutol rapidly the growth is not inhibited before 24 hours In animal experiments ethambutol given orally manifests same therapeutic activity as that of isoniazid when injected parenterally ethambutol is superior to streptomycin Bacterial resistance to ethambutol develops on *in vivo* when it is given alone in treatment of tuberculosis

Indications Etinol is indicated in cases of primary pulmonary tuberculosis and extra pulmonary forms of tuberculosis such as miliary tuberculosis tuberculous meningitis and tuberculosis of the bones and joints along with other antituberculous drugs The selection of the other antituberculous drug should be based on the *in vitro* sensitivity test safety acceptability and clinical experience

Dosage In patients who have not received any antituberculous therapy before the initial dosage of Etinol recommended in combination is as follows The required dosage of Etinol is preferably given once a day Etinol is usually combined with isoniazid streptomycin or with rifampicin Usually the dose of Etinol ranges from 15-25 mg/kg body weight A dose of 15 mg/kg is

recommended for initial treatment In those cases where retreatment is desired the initial dose of Etinol is 25 mg/kg body weight for 8 weeks The dose is then reduced to 15 mg/kg body weight When the patient has received a course of antituberculous drug therapy before Etinol should be used in combination with any other antituberculous drug after carrying out the *in vitro* sensitivity tests

Contraindications

1 Known hypersensitivity
2 Optic neuritis

Precautions

1 Thorough examination of the eyes is a must before starting treatment with Etinol

2 Suitable adjustment of dosage is necessary for patients with impaired renal function

3 Use of Etinol in children under 13 years of age is not recommended

Untoward Effects Etinol produces very few reactions Only less than 2% of the patients receiving 15 mg/kg develops untoward reactions Out of this only 8% experience diminished visual acuity 5% suffer from rash and 3% develop drug fever The other untoward effects which have been observed are pruritus joint pain gastrointestinal upset abdominal pain malaise headache dizziness mental confusion disorientation and possible hallucination Optic neuritis resulting in decreased visual acuity and loss of ability to perceive green colour This reaction is proportional to the dose and is observed in 15% of the patients receiving 50 mg/kg 5% of the patients receiving 25 mg/kg per day and less than 1% patients receiving 15 mg/kg/day The intensity of visual difficulty is also related to the duration of therapy and it may be unilateral or bilateral Recovery usually occurs when ethambutol is withdrawn The time required is a function of the degree of visual impairment

Increased concentration of urate in the blood may occur due to decreased renal excretion of uric acid This change may be detectable as early as 24 hours after a single dose or as late as 90 days after treatment is started This untoward effect is likely to be enhanced by isoniazid and pyridoxine

Presentation

Etinol Tablets Each Tablet contains 400 mg of ethambutol hydrochloride Strips of 10 tablets and boxes of 10 strips of 10 s

Expiration date 24 months

FUNGIZONE® INTRAVENOUS — Sterile Powder

Amphotericin B for Injection

Fungizone Intravenous (Amphotericin B for Injection) is an antifungal antibiotic derived from a strain of *Streptomyces nodosus* Crystalline amphotericin B is insoluble in water therefore the antibiotic is solubilized by the

addition of sodium desoxycholate to form a mixture which provides a colloidal dispersion for parenteral administration

Action

Microbiology

Amphotericin B shows a high order of *in vitro* activity against many species of fungi *Histoplasma capsulatum Coccidiodes immitis Candida* species *Blastomyces dermatitidis Rhodotorula Cryptococcus neoformans Sporotrichum schenckii Mucor mucedo* and *Aspergillus fumigatus* are all inhibited by concentrations of amphotericin B ranging from 0 03 to 1 0 mcg/ml *in vitro* The antibiotic is without effect on bacteria rickettsiae and viruses

Clinical Pharmacology

Amphotericin B is fungistatic or fungicidal depending on the concentration obtained in body fluids and the susceptibility of the fungus The drug probably acts by binding to sterols in the fungus cell membrane with a resultant change in membrane permeability which allows leakage of a variety of small molecules Mammalian cell membranes also contain ste rols and it has been suggested that the damage to human cells and fungal cells may share common mechanisms

An initial intravenous infusion of 1 to 5 mg of amphotericin B per day gradually increased to 0 65 mg/kg daily produces peak plasma concentra tions of approximately 2 to 4 mcg/ml which can persist between doses since the plasma half-life of amphotericin B is about 24 hours (For recom mended dosages see *Administration and Dosage* section) About 10% of the drug is bound to plasma proteins

Amphotericin B is excreted very slowly by the kidneys with 2 to 5% of a given dose being excreted in biologically active form After treatment is dis continued the drug can be detected in the urine for at least seven weeks The cumulative urinary output over a seven day period amounts to approxi mately 40% of the amount of drug infused

Details of tissue distribution and possible metabolic pathways are not known

Indications Fungizone Intravenous should be administered primarily to patients with progressive potentially fatal infections This potent drug should not be used to treat common inapparent forms of fungal disease which show only positive skin or serologic tests

Fungizone Intravenous (Amphotericin B for Injection) is specifically intend ed to treat cryptococcosis (torulosis) North American blastomycosis the disseminated forms of moniliasis coccidioidomycosis and histoplasmosis mucormycosis (phycomycosis) caused by species of the genera *Mucor Rhizopus Absidia Entomophthora* and *Basidiobolus* sporotrichosis *(Sporotrichum schenkii)* aspergillosis *(Aspergillus fumigatus)*

Amphotericin B may be helpful in the treatment of American mucocuta neous leishmaniasis but is not the drug of choice in primary therapy

Contraindications This product is contraindicated in those patients who have shown hypersensitivity to it unless in the opinion of the physician the

condition requiring treatment is life threatening and amenable only to amphotericin B therapy

Warning Amphotericin B is frequently the only effective treatment available for a potentially fatal fungal disease In each case its possible life-saving benefit must be balanced against the untoward and dangerous side effects

This drug should be used *primarily* for treatment of patients with pro gressive and potentially fatal fungal infections it should not be used to treat the common clinically inapparent forms of fungal disease which show only positive skin or serologic tests

Usage in Pregnancy Safety for use in pregnancy has not been established therefore it should be used during pregnancy only if the possible benefits to be derived outweigh the potential risks involved

Precautions Prolonged therapy with amphotericin B is usually necessary Un pleasant reactions are quite common when the drug is given parenteral ly at therapeutic dosage levels **Some of these reactions are potentially dangerous** Hence amphotericin B should be used parenterally only in hospitalized patients under close medical supervision and should be re served for those patients or those under close clinical observation by medically trained personnel and should be reserved for those patients in whom a diagnosis of progressive potentially fatal forms of susceptible mycotic infections has been firmly established by positive culture or histo logic study

Corticosteroids should not be administered concomitantly unless they are necessary to control drug reactions Other nephrotoxic antibiotics and antineoplastic agents such as nitrogen mustard should not be given con comitantly except with great caution

Laboratory facilities must be available to perform blood urea nitrogen and serum creatinine or endogenous creatinine clearance tests These deter minations should be made at least weekly during therapy If the BUN exceeds 40 mg per 100 ml or the serum creatinine exceeds 3 0 mg per 100 ml the drug should be discontinued or the dosage markedly reduced until renal function is improved Weekly haemograms and serum potas sium determinations are also advisable Low serum magnesium levels have also been noted during treatment with amphotericin B Therapy should be discontinued if liver funtion test results (elevated bromsulphalein alkaline phosphatase and bilirubin) are abnormal

Whenever medication is interrupted for a period longer than 7 days therapy should be resumed by starting with the lowest dosage level e g 0 25 mg/kg of body weight and increased gradually as outlined under *Administration and Dosage*

Adverse Reactions While some few patients may tolerate full intravenous doses of amphotericin B without difficulty most will exhibit some intoler ance often at less than the full therapeutic dosage They may be made less severe by giving aspirin antihistaminics and antiemetics Administration of the drug on alternate days may decrease anorexia and phlebitis Intra venous administration of small doses of adrenal corticosteroids just prior to or during the amphotericin B infusion may decrease febrile reactions

The dosage and duration of such corticosteroid therapy should be kept to a min mum Adding a small amount of heparin to the infusion may lessen the incidence of thrombophlebitis Extravasation may cause chemical irritation

The adverse reactions that are most commonly observed are Fever (some times with shaking chills) headache anorexia weight loss nausea and vomiting malaise dyspepsia diarrhoea generalized pain including muscle and joint pains cramping epigastric pain and local venous pain at the injec tion site with phlebitis and thrombophlebitis and normochromic normo cytic anaemia Abnormal renal function including hypokalaemia azotemia hyposthenuria renal tubular acidosis and nephrocalcinosis is also commonly observed and usually improves upon interruption of therapy however some permanent impairment often occurs especially in those patients receiving large amounts (over 5 g) of amphotericin B Supple mental alkali medication may decrease renal tubular acidosis complica tions

The following adverse reactions occur less frequently or rarely Anuria oliguria cardiovascular toxicity including arrhythmias ventricular fibrilla tion cardiac arrest hypertension and hypotension coagulation defects thrombocytopenia leucopenia agranulocytosis eosinophilia leucocytosis melena or haemorrhagic gastroenteritis maculopapular rash hearing loss tinnitus transient vertigo blurred vision or diplopia peripheral neuropathy convulsions and other neurologic symptoms pruritus (without rash) ana phylactoid reactions acute liver failure and flushing

Administration and Dosage Fungizone Intravenous (Amphotericin B for Injec tion) should be administered by *slow* intravenous infusion Intravenous infusion should be given over a period of approximately 6 hours observing the usual precautions for intravenous therapy The recommended concen tration for intravenous infusion is 0 1 mg/ml (1 mg/10 ml)

Dosage must be adjusted to the specific requirements of each patient since tolerance to amphotericin B varies individually Therapy is usually instituted with a daily dose of 0 25 mg/kg of body weight and **gradually** increased as tolerance permits There are insufficient data presently avail able to define total dosage requirements and duration of treatment neces sary for eradication of mycoses such as phycomycosis The optimal dose is unknown Total daily dosage may range up to 1 0 mg/kg of body weight or alternate day dosages ranging up to 1 5 mg/kg Several months of therapy are usually necessary a shorter period of therapy may produce an inade quate response and lead to relapse

CAUTION Under no circumstances should a total daily dosage of 1 5 mg/kg be exceeded

Therapy with intravenous amphotericin B for sporotrichosis has ranged up to 9 months The usual dose per injection is 20 mg

Aspergillosis has been treated with amphotericin B intravenously for a period up to 1 1 months with total dose up to 3 6 g

Rhinocerebral phycomycosis a fulminating disease generally occurs in association with diabetic ketoacidosis It is therefore imperative that rapid restoration of diabetic control be instituted before successful treatment

with Fungizone Intravenous (Amphotericin B for Injection) can be accomplished In contradistinction pulmonary phycomycosis which is more common in association with haematologic malignancies is often an incidental finding at autopsy A cumulative dose of at least 3 g of amphotericin B is recommended Although a total dose of 3 to 4 g will infrequently cause lasting renal impairment this would seem a reasonable minimum where there is clinical evidence of invasion of the deep tissues since rhinocerebral phycomycosis usually follows a rapidly fatal course the therapeutic approach must necessarily be more aggressive than that used in more indolent mycoses

Preparation of Solutions The dry powder should be reconstituted as follows An initial concentrate of 5 mg amphotericin B per ml is first prepared by adding 10 ml Sterile Water for Injection *without a bacteriostatic agent* to the vial of dry powder and shaking the vial until the solution is clear The infusion solution providing 0 1 mg amphotericin B per ml is then obtained by further dilution (1 50) with 5% Dextrose Injection *of pH above 4 2* The pH of each container of Dextrose Injection should be ascertained before use Commercial Dextrose Injection usually has a pH above 4 2 however if it is below 4 2 then 1 or 2 ml of buffer should be added to the Dextrose Injection before it is used to dilute the concentrated solution of amphotericin B The recommended buffer has the following composition

Dibasic sodium phosphate (anhydrous)	1 59 g
Monobasic sodium phosphate (anhydrous)	0 96 g
Water for Injection	qs 100 0 ml

The buffer should be sterilized before it is added to the Dextrose Injection either by filtration through a bacterial retentive stone mat or membrane or by autoclaving for 30 minutes at 15 lb pressure (121 C)

Caution Aseptic technique must be strictly observed in all handling since no preservative or bacteriostatic agent is present in the antibiotic or in the materials used to prepare it for administration **All entries into the vial or into the diluents must be made with sterile needle Do not reconstitute with saline solutions The use of any diluent other than the ones recommended or the presence of a bacteriostatic agent** (e g benzyl alcohol) **in the diluent may cause precipitation of the antibiotic Do not use the initial concentrate or the infusion solution if there is any evidence of precipitation or foreign matter in either one**

An in line membrane filter may be used for intravenous infusion of amphotericin B **however the mean pore diameter of the filter should not be less than 1 0 micron in order to assure passage of the antibiotic dispersion**

Presentation Fungizone Intravenous (Amphotericin B for Injection) is supplied in vials as a sterile lyophilized powder providing 50 mg amphotericin B and 41 mg sodium desoxycholate with 25 2 mg sodium phosphates as a buffer At the time of manufacture the air in the container is replaced by nitrogen

Expiration date 12 months

Note Prior to reconstitution Fungizone Intravenous (Amphotericin B for Injection) should be stored in the refrigerator protected against exposure to light The concentrate (5 mg amphotericin B per ml after reconstitution with 10 ml Sterile Water for Injection) may be stored in the dark at room temperature for 24 hours or at refrigerator temperatures for one week with minimal loss of potency and clarity Any unused material should then be discarded Solutions prepared for intravenous infusion (0 1 mg or less amphotericin B per ml) should be used promtly after preparation and should be protected from light during administration

FUNGIZONE®

Tablets

Amphotericin B

Fungizone Amphotericin B is a polyene antibiotic produced by a strain of *Streptomyces nodosus* Each Fungizone Tablet contains 100 mg amphotericin B

Action Fungizone inhibits the growth of a wide variety of yeasts and yeast like fungi The drug is well tolerated as an oral antifungal agent and its efficacy is dependable for the prophylaxis or treatment of intestinal candidiasis In humans as in experimental animals oral administration of amphotericin B in high doses produced at most only low blood levels (0 05 mcg/ml) due to poor absorption of the drug from the gastrointestinal tract Most of the orally administered drug is eliminated via the faeces

Indications Fungizone Tablets are indicated for the prophylaxis or treatment of intestinal candidiasis including that sometimes induced by the broad spectrum antibiotics and for the suppression of any intestinal reservoir of *Candida albicans* which may complicate cutaneous mucocutaneous or vaginal candidiasis For the latter purpose Fungizone Tablets should be employed as an adjunct to other specific topical therapeutic measures

Dosage and Administration The suggested dosage for both adult and paediatric patient is (a) *prophylactic* 50 or 100 mg q i d (b) *therapeutic* 100 mg q i d However if desired substantially higher dosage may be employed without serious side effects or significant toxicity The tablets may be administered to infants and young children by pulverizing combining with water or milk and utilizing a dropper

Toxicity Probably because of its very limited absorption Fungizone Tablets are virtually nontoxic and non sensitizing and are well tolerated by all age groups including debilitated infants even on prolonged administration

Presentation Bottles of 12 tablets

Expiration date 12 months

FUNGIZONE® S OTIC DROPS — Liquid

Amphotericin B with Neomycin Gramicidin (Spectrocin®)

Fungizone S Otic Drops is Amphotericin B with Spectrocin (Neomycin and Gramicidin) in propylene glycol

Each ml of Fungizone-S Otic Drops contains

Neomycin base		3 5 mg
Gramicidin		1 0 mg
Amphotericin B		30 0 mg
Benzocaine		14 0 mg
Propylene glycol Glycerin (3 1) base	qs	1 ml

Action and Uses Fungizone-S Otic Drops have bactericidal and fungicidal action It provides a combination of antibacterial and antifungal antibiotics effective against a wide variety of gram positive and gram-negative organisms including fungi commonly encountered in otic infections

Fungizone-S Otic Drops are indicated for the treatment of infections pain and itching associated with otitis externa otitis media with a perforated tympanic membrane post operative aural cavities and furunculosis of the ear

Contraindications This product is contraindicated in individuals with a history of hypersensitivity to any of its components

Adverse Reactions Hypersensitivity to neomycin may occur and this antibiotic may itself cause an allergic otitis externa Systemic neomycin toxicity has occurred rarely following topical administration tinnitus and deafness having been reported The possibility of deafness is increased if perforation of the ear drum exists Gramicidin if allowed to come in close proximity to the subarachnoid space may cause a chemical arachnoiditis

Administration and Dosage Prior to administration of Fungizone S Otic Drops all wax and epithelial debris should be removed and the tympanic membrane inspected Three to four drops are instilled in the infected ear two to three times daily The drops should be instilled with the affected ear turned upward and this position should be maintained for a minute to facilitate penetration of the drops into the ear canal

Care should be taken to shake the bottle well before using

Presentation Bottles of 5 ml with dropper

Expiration date 12 months

HYDREA® — Capsules

Hydroxyurea

Hydrea (Hydroxyurea) is an antineoplastic agent available for oral use as capsules providing 500 mg hydroxyurea Hydroxyurea occurs as an essentially tasteless white crystalline powder

Action Mechanism of Action The precise mechanism by which hydroxyurea produces its cytotoxic effects cannot at present be described However the reports of various studies in tissue culture in rats and man lend support to the hypothesis that hydroxyurea causes an immediate inhibition of DNA synthesis without interfering with the synthesis of ribonucleic acid or of protein This hypothesis explains why under certain conditions hydroxy urea may induce teratogenic effects

Three mechanisms of action have been postulated for the increased ef fectiveness of concomitant use of hydroxyurea therapy with irradiation on squamous cell (epidermoid) carcinomas of the head and neck *In vitro* studies utilizing Chinese hamster cells suggest that hydroxyurea (1) is lethal to normally radioresistant S stage cells and (2) holds other cells of the cell cycle in the G1 or pre DNA synthesis stage where they are most susceptible to the effects of irradiation The third mechanism of action has been theorized on the basis of *in vitro* studies of HeLa cells It appears that hydroxyurea by inhibition of DNA synthesis hinders the normal repair process of cells damaged but not killed by irradiation thereby decreasing their survival rate RNA and protein syntheses have shown no alteration

Absorption Metabolism Fate and Excretion After oral administration in man hydroxyurea is readily absorbed from the gastrointestinal tract The drug reaches peak serum concentrations within 2 hours by 24 hours the concentration in the serum is essentially zero Approximately 80% of an oral or intravenous dose of 7 30 mg/kg may be recovered in the urine within 12 hours

Indications Significant tumour response to Hydrea (Hydroxyurea) has been demonstrated in melanoma resistant chronic myelocytic leukaemia and recurrent matastatic or inoperable carcinoma of the ovary

It is useful for quickly reducing very high white cell counts in patients with acute myelogenous leukaemia or chronic myelogenous leukaemia in blast ic crisis who have rapidly proliferating disease A large dose will significant ly reduce myeloblast counts within 24 hours with the nadir occurring at 3 days

Hydrea used concomitantly with irradiation therapy is intended for use in the local control of primary squamous cell (epidermoid) carcinomas of the head and neck excluding the lip

Contraindications Hydroxyurea is contraindicated in patients with marked bone marrow depression i e leucopenia (less than 2500 WBC) or throm bocytopenia (less then 100 000) or severe anaemia

Warnings Treatment with hydroxyurea should not be initiated if bone marrow function is markedly depressed (see *Contraindications*) Bone marrow sup pression may occur and leucopenia is generally its first and most common manifestation Thrombocytopenia and anaemia occur less often and are seldom seen without a preceding leucopenia However the recovery from myelosuppression is rapid when therapy is interrupted It should be borne in mind that bone marrow depression is more likely in patients who have previously received radiotherapy or cytotoxic cancer chemotherapeutic agents hydroxyurea should be used cautiously in such patients

Patients who have received irradiation therapy in the past may have an exacerbation of post irradiation erythema

Severe anaemia must be corrected with whole blood replacement before initiating therapy with hydroxyurea

Erythrocytic abnormalities Magaloblastic erythropoiesis which is self limiting is often seen early in the course of hydroxyurea therapy The morphologic change resembles pernicious anaemia but is not related to vitamin B_1 or folic acid deficiency Hydroxyurea may also delay plasma iron clearance and reduce the rate of iron utilization by erythrocytes but it does not appear to alter the red blood cell survival time

Hydroxyurea should be used with caution in patients with marked renal dysfunction

Elderly patients may be more sensitive to the effect of hydroxyurea and may require a lower dose regimen

It should be noted that abnormal changes in clinical laboratory data (see *Adverse Reactions*) are difficult to explain in cancer patients during drug therapy Changes toward normal are often due to an improvement in the function of an organ changes to abnormal levels are more likely due to progressive disease

Usage in Pregnancy Drugs which affect DNA synthesis such as hydroxyurea may be potential mutagenic agents The physician should carefully consi der this possibility before administering this drug to male or female patients who may contemplate conception

Hydrea (Hydroxyurea) is a known teratogenic agent in animals Therefore hydroxyurea should not be used in women who are or may become preg nant unless in the judgement of the physician the potential benefits out weigh the possible hazards

Precautions Therapy with Hydrea requires close supervision The complete status of the blood including bone marrow examination if indicated as well as kidney function and liver function should be determined prior to and repeatedly during treatment The determination of the haemoglobin level total leucocyte counts and platelet counts should be performed at least once a week throughout the course of Hydrea (Hydroxyurea) therapy If the white blood cell count decreases to less than 2500/mm^3 or the platelet count to less than 100 000/mm^3 therapy should be interrupted until the values rise significantly toward normal levels Anaemia if it occurs should be managed with whole blood replacement without interrupting hydroxy urea therapy

Adverse Reactions Adverse reactions have been primarily bone marrow de pression (leucopenia anaemia and occasionally thrombocytopenia) and less frequently gastrointestinal symptoms (stomatitis anorexia nausea vomiting diarrhoea and constipation) and dermatological reactions such as maculopapular rash and facial erythema Dysuria and alopecia occur very rarely Large doses may produce moderate drowsiness Neurological disturbances have occurred extremely rarely and were limited to headache dizziness disorientation hallucinations and convulsions Their relationship to hydroxyurea administration is questionable because cerebral metastatic

disease was not excluded Hydroxyurea occasionally may cause temporary impairment of renal tubular function accompanied by elevations in serum uric acid BUN and creatinine levels Abnormal BSP retention has been reported

Adverse reactions observed with combined hydroxyurea and irradiation therapy are similar to those reported with the use of hydroxyurea alone These effects primarily include bone marrow depression (anaemia and leucopenia) and gastric irritation Almost all patients receiving an adequate course of combined hydroxyurea and irradiation therapy will demonstrate concurrent leucopenia Platelet depression (less than 100 000 cells/mm^3) has occurred rarely and only in the presence of marked leucopenia Gastric distress has also been reported with irradiation alone and also in combination with hydroxyurea therapy

It should be borne in mind that therapeutic doses of irradiation alone produce the same adverse reactions as hydroxyurea combined therapy may cause an increase in the incidence and severity of these side effects

Although inflammation of the mucous membranes at the irradiated site (mucositis) is attributed to irradiation alone some investigators believe that the more severe cases are due to combination therapy

Administration and Dosage Because of the rarity of melanoma resistant chronic myelocytic leukaemia carcinoma of the ovary and carcinomas of the head and neck in children dosage regimens have not been established

All dosage should be based on the patient s actual or ideal weight which ever is less

Note If the patient prefers or is unable to swallow capsules the contents of the capsules may be emptied into a glass of water and taken immediately Some inert material used as a vehicle in the capsule may not dissolve and may float on the surface

Solid Tumours
Intermittent Therapy 80 mg/kg
administered orally as a *single*
dose every *third* day
Continuous Therapy 20 30 mg/kg
administered orally as a *single*
dose *daily*

The intermittent dosage schedule offers the advantage of reduced toxicity since patients on this dosage regimen have rarely required complete discontinuance of therapy because of toxicity

Concomitant Therapy with Irradiation *(Carcinoma of the head and neck)* – 80 mg/kg administered orally as a *single* dose every *third* day

Administration of Hydrea (Hydroxyurea) should be begun at least seven days before initiation of irradiation and continued during radiotherapy as well as indefinitely afterwards provided that the patient may be kept under adequate observation and evidences no unusual or severe reactions

Irradiation should be given at the maximum dose considered appropriate for the particular therapeutic situation adjustment of irradiation dosage is not usually necessary when Hydrea is used concomitantly

Resistant Chronic Myelocytic Leukaemia
Until the intermittent therapy regimen has been evaluated CONTINUOUS therapy (20 30 mg/kg administered orally as a *single* dose *daily*) is recommended

An adequate trial period for determining the antineoplastic effectiveness of Hydrea is 6 weeks of therapy When there is regression in tumour size or arrest in tumour growth therapy should be continued indefinitely Therapy should be interrupted if the white blood cell count drops below 2500/mm^3 or the platelet count below 100 000/mm^3 In these cases the counts should be rechecked after 3 days and therapy resumed when the counts rise significantly toward normal values Since the haematopoietic rebound is prompt it is usually necessary to omit only a few doses If prompt rebound has not occurred during combined hydroxyurea and irradiation therapy irradiation may also be interrupted However the need for post ponement of irradiation has been rare radiotherapy has usually been con tinued using the recommended dosage and technique Anaemia if it occurs should be corrected with whole blood replacement without inter rupting hydroxyurea therapy Because haematopoiesis may be compro mised by extensive irradiation or by other antineoplastic agents it is recom mended that Hydrea (Hydroxyurea) be administered cautiously to patients who have recently received extensive radiation therapy or chemotherapy with other cytotoxic drugs

Pain or discomfort from inflammation of the mucous membranes at the irradiated site (mucositis) is usually controlled by measures such as topical anaesthetics and orally administered analgesics If the reaction is severe hydroxyurea therapy may be temporarily interrupted if it is extremely severe irradiation dosage may in addition be temporarily postponed How ever it has rarely been necessary to terminate these therapies

Severe gastric distress such as nausea vomiting and anorexia resulting from combined therapy may usually be controlled by temporary interruption of Hydrea (Hydroxyurea) administration rarely has the additional interrup tion of irradiation been necessary

Presentation Strips of 6 capsules and boxes of 2 strips of 6 s

Note May be stored at room temperature

HYGIERUB* — Ointment

Hygienic Rub for Cold

Hygierub ointment to treat common cold hygienically

Each shell of Hygierub contains

Camphor	60 %
Menthol	28 %
Thymol	01 %
Turpentine Oil	61 %
Eucalyptus Oil	60 %
Nutmeg Oil	055 %

Action The ingredients of Hygierub are aromatic substances and volatile oils When applied on the affected parts Hygierub provides warmth and relief by the counter irritant effect of the volatile oils This effect gives symptomatic relief to a patient suffering from cold and headache Vopour of Hygierub can also be inhaled by putting it in a steaming hot water The reflexly induced vasoconstriction mediates a mild nasopharyngeal decongestant effect

Advantages

- Single shell for each application
- Each application is free from contamination
- Each shell is a pack in itself and thereby the efficacy of the ingredients is retained
- Each application is a fresh one assuring full potency of volatile oils
- It is convenient to carry
- It is economical

Direction for use

a) *External application* Detach one shell from the strip Peel open the shell and apply over the affected areas of the body

b) *Inhalation* Peel the foil and drop one or two shells in steaming water

Presentation Strips of 4 shells and boxes of 25 strips of 4 s

KENACOMB® — Ointment

Triamcinolone Acetonide Neomycin - Gramicidin (Spectrocin®) and Nystatin (Mycostatin®)

Kenacomb is a highly effective dermatologic preparation that has four basic therapeutic effects anti inflammatory antipruritic antibacterial and antifungal It is especially formulated for skin conditions caused or compli cated by bacterial and/or monilial infection and where potent dependable anti inflammatory antipruritic action is desired

Each gramme of Kenacomb supplies

Triamcinolone Acetonide	1 0 mg (0 1%)
Neomycin Base (as sulphate)	2 5 mg
Gramicidin	0 25 mg
Nystatin	100 000 units

- TRIAMCINOLONE ACETONIDE is an outstanding topical corticosteroid Proved clinically superior wherever topical corticoids are indicated triamcinolone acetonide is distinguished by its marked anti-inflammatory antipruritic antiallergic effects It provides rapid complete often prolonged relief of itching burning and cutaneous inflammation

Triamcinolone acetonide is known for its superiority over hydrocortisone and prednisolone and is frequently effective in those instances where hydrocortisone and other corticosteroids fail to bring about a good or complete therapeutic response

- SPECTROCIN combines the broad spectrum activities of two potent topical antibiotics neomycin and gramicidin The joint action of these powerful anti infectives provide comprehensive antibacterial therapy against a wide range of gram-positive and gram negative bacteria including those responsible for most bacterial skin infections

- MYCOSTATIN is the antibiotic of choice for treating or preventing cutaneous *Candida* (Monilia) *albicans* infections The first safe antifungal anti biotic Mycostatin is uniformly effective in most local monilial infections

Plastobase® (Plasticized Hydrocarbon Gel) the vehicle in Kenacomb Ointment is a combination of 95% Liquid Petrolatum and 5% polyethylene an inert plastic Liquid petrolatum is thickened and retained in gel form by a matrix of solid polyethylene As used in Kenacomb Ointment Plastobase provides fast regular and thorough release of medicaments and uniform dispersion of medicaments even at elevated temperatures Consistently soft Kenacomb Ointment is easily applied to the skin and is non- running at body temperature It imparts a velvety non-greasy feel to the skin and can be readily removed

Advantages

- four basic therapeutic effects in one preparation–anti-inflammatory antipruritic antibacterial antifungal
- dramatically effective–provides rapid complete often prolonged relief of itching burning and inflammation frequently when other topical steroids have failed
- a potent anti infective–combats or prevents bacterial and/or monilial infections
- unusually well tolerated
- excellent patient acceptance

Indications

- superficial bacterial infections
- cutaneous moniliasis
- lichen simplex chronicus
- anogenital pruritus (pruritus ani et vulvae)
- infantile eczema

The following conditions when threatened or complicated by bacterial and/or monilial superinfection

- atopic dermatitis
- eczematoid dermatitis
- stasis dermatitis
- nummular dermatitis
- contact dermatitis
- exudative dermatitis
- seborrhoeic dermatitis
- neurodermatitis
- dermatitis venenata

Administration Apply a thin film to the affected area 2 to 3 times daily

Contraindications Kenacomb is contraindicated in tuberculous and most viral lesions of the skin herpes simplex vaccinia and varicella particularly It is also contraindicated in fungal lesions of the skin except candidiasis and in patients with a history of hypersensitivity to any of its components

Precautions Kenacomb has been extremely well tolerated locally Systemic toxicity has not been observed with topical applications of triamcinolone acetonide or any of the other active cmponents Sensitivity reactions to topically applied nystatin triamcinolone acetonide neomycin or gramicidin are only rarely encountered With prolonged use of steroids in intertriginous areas or under occlusive dressings striae may occur Systemic side effects are possibility when topical steroid preparations are used over large areas or over prolonged periods

Presentation Tubes of 2 5 g and 5 g

Expiration date 18 months May be stored at room temperature

KENACORT® Tablets

Triamcinolone

Kenacort Triamcinolone is the 9 alpha fluoro 16 alpha hydroxy derivative of prednisolone Besides being a potent anti inflammatory antirheumatic and anti allergic agent Kenacort differs from other glucocorticoids in some aspects of its clinical utility For example in the usual doses it rarely causes sodium of fluid retention voracious appetite and its associated weight gain common with some glucocorticoids are very unusual with Kenacort Thus for patients in whom such side effects are to be avoided Kenacort may be the drug of choice Psychic stimulation does not usually occur and patients in whom other steroids have induced euphoria or mental stimula tion would not be likely to experience the same effects with Kenacort

Kenacort as with other newer corticosteroids appears to persist in the blood for a longer time than hydrocortisone (cortisol)

Plasma biologic half life of injected steroid *(in minutes)*

Corticosteroid	Man[1]	Man[2]	Dog
Hydrocortisone	101	120	44 52
Prednisolone	200	180	60 71
Methylprednisolone	–	210	80 9
Dexamethasone	200	–	60
Triamcinolone	>300	–	116 7

1 *Melby J C Med Clin North America* 45 875 *(July)* 1961
2 *McGavack T H Nebraska J Med* 44 377 *(Aug.)* 1959
3 *Florini J R et al J Pharmacol and Exper Therap* 131 287 *(Mar.)* 1961

Historically corticoids have been administered on a t i d or q i d basis In clinical studies Kenacort has proved efficacious even when longer inter vals between doses were employed Single daily doses of Kenacort have been used effectively in the dermatoses allergic disorders and mild connective tissue diseases (acute bursitis myositis fibrositis etc) In rheumatoid arthritis the incidence of effective control using the single daily dose was considerably lower but occurred often enough to make the regimen worthy of trial in this condition Divided dosage with Kenacort continues to be effective for many other patients with corticosteroid responsive conditions

Advantages

- effective anti inflammatory antirheumatic and anti allergic action
- sodium or fluid retention rare
- secondary hypertension rare
- undesirable psychic stimulation does not usually occur
- voracious appetite unusual
- no need for dietary salt restriction

Indications Bronchial asthma other allergic disorders dermatoses psoriasis (except mild uncomplicated) nephrotic syndrome pulmonary emphysema pulmonary fibrosis acute rheumatic fever vasomotor rhinitis urticaria angioneurotic oedema rheumatoid arthritis the lymphatic leukaemias lymphosarcoma Hodgkin s disease disseminated lupus erythematosus In other forms of leukaemia where for example haemolytic anaemia or thrombocytopenia occur Kenacort may be helpful It has been used successfully in acute bursitis sprue uveitis–and such blood dyscrasias as chronic eosinophilia thrombocytopenic purpura and auto immune haemo lytic anaemias The drug may also be of value when other corticosteroids have failed or have reached a limit of usefulness in steroid responsive conditions

Contraindications Although corticosteroids have been used experimentally in the treatment of active tuberculosis the disease whether active latent or healed is still usually considered a *contraindication* to their use Corticoids are also contraindicated in ocular herpes simplex and acute psychosis and

relatively so in presence of active peptic ulcer acute glomerulonephritis and infections which cannot be controlled by antibiotics The use of ster oids in patients with myasthenia gravis may aggravate myasthenic symp toms and should therefore be given with proper precautions Cortico steroids are not recommended for pregnant patients particularly during the first trimester except when the disease for which they are indicated is very severe In newborns of mothers who have received corticoid therapy the possible occurrence of hypoadrenalism should be borne in mind When considering triamcinolone treatment in the presence of any of the follow ing the need for steroid therapy must be thoroughly weighed against the possible deleterious effects on the contraindicated condition diverticulitis fresh intestinal anastomoses thrombophlebitis psychotic tendencies chronic nephritis metastatic carcinoma osteoporosis and history of peptic ulcer

Adverse Reactions and Precautions Triamcinolone like all potent steroids should be used under close clinical supervision Weight gain oedema and hypertension the usual unwanted steroid effects usually do not occur patients must be observed for the less obvious undesirable effects All corticosteroids may mask symptoms of infection and permit spread of an invading organism If questionable findings are encountered it may be advisable to interrupt triamcinolone therapy until an accurate diagnosis is made

In acute and chronic *bacterial* infections triamcinolone should only be used in conjunction with suitable antibiotic or chemotherapeutic agents The drug should be withheld during acute *viral* infections such as ocular herpes simplex and varicella Steroid patients must be watched carefully for the development of osteoporosis and spontaneous fracture peptic ulcer or epigastric distress Cushingoid changes such as facial rounding buffalo hump and other signs of fat deposition may be seen in some cases Purpura flushing of the face sweating acne striae hirsutism vertigo and headache may be encountered The growth suppressing effects of cortico steroids in children should be considered when triamcinolone is admini stered to the paediatric age group

Thromboembolism aseptic necrosis of the hip necrotizing angiitis acute pancreatitis and ulcerative oesophagitis are other possible side effects of steroid therapy

A liberal protein intake is essential for patients receiving triamcinolone since it does not stimulate appetite On prolonged therapy most patients have a tendency to gradual weight loss sometimes associated with nega tive nitrogen balance As with all corticoids wasting and weakness of skeletal muscle may occur in some patients Anabolic steroids appear to be useful in maintaining nitrogen equilibrium Diabetic patients frequently re quire an increase in insulin dosage latent diabetes mellitus may become manifest during steroid therapy

While in rare instances increased intracranial pressure and papilloedema have been reported to occur after administration of corticosteroids includ ing triamcinolone the mechanism of action has not been elucidated The possible association of posterior subcapsular cataracts with the admini stration of high dosage long term systemic corticosteroid therapy has

been presented in the literature For this and other reasons long term administration of corticoids should be kept at minimum dosage levels

In therapeutic doses glucocorticoids depress the function of the adrenal cortex To avoid adrenal insufficiency therapy should be withdrawn gradually (2 mg every two to three days) particularly when patients are receiving large doses or prolonged treatment Undue stress i e surgery trauma severe illness during or within a year after triamcinolone treatment has been terminated calls for prompt institution of adequate supportive measures for the duration of the stress During treatment Kenacort dosage should be increased temporarily supportive measures in the year after treatment should include ACTH and in some situations of severe stress hydrocortisone or cortisone

Dosage Individual requirements and the disease under treatment determine Kenacort dosage A single daily dose given either in the morning or at bedtime depending on the clinical situation may be satisfactory for initial or maintenance therapy in many patients others will require a divided daily dosage regimen such as b i d to q i d administration Initial daily dosage generally ranges from 8 to 32 mg for adults and from 4 to 12 mg for children under 25 kg Children over 25 kg may be given adult dosage It may be necessary to administer initial adult dosage in children under 25 kg After a satisfactory response the adult dosage is reduced *gradually* by 2 mg every two to three days to the optimal maintenace level Maintenance dosage in children is regulated in terms of clinical response

Intermittent Kenacort therapy employing other dosage intervals has been successful in the nephrotic syndrome and this use has also been reported in the management of juvenile rheumatoid arthritis and in certain chronic dermatoses in addition to patient convenience it has been suggested that once daily administration of corticosteroid is less likely to interfere with diurnal rhythm of the spontaneously secreting adrenal gland if this is the reason for single daily dose therapy the dose should be given in the morning In other patients i e the arthritic who complains of morning stiffness or the asthmatic who needs protection during the night a nocturnal dose would be more desirable

The 8 mg tablet suggests an added convenience for those patients responsive to once a day or other intermittent oral Kenacort dosage

Patient transfers from other corticosteroids Initially substitute 4 mg Kenacort for each of the following

25 mg cortisone	4 mg methylprednisolone
20 mg hydrocortisone	0 75 mg dexamethasone
5 mg prednisone	2 mg paramethasone
5 mg prednisolone	

Thereafter dosage should be adjusted according to individual response

KENACORT THERAPY GUIDE

Condition	*Initial Daily Dosage*	*Maintenance Daily Dosage*
bronchial asthma	adult [1] 8 16 mg children 8 12 mg	adults 2 8 mg children 1 4 mg
allergic disorders	adults [1] 8 16 mg children 4 8 mg	adults 4 16 mg children 2 mg or less
dermatoses	adults [1] 8 20 mg children 4 12 mg	adults and children 2 mg or less
psoriasis [3] acute exacerbations	adults 4 32 mg (advocated for short term control only)	adults 1 16 mg
nephrotic syndrome	adults and children 20 48 mg to diuresi (usually within 7 10 days)	adults and children intermittent therapy 8 16 mg for 3 consecutive days per week
pulmonary emphysema pulmonary fibrosis [4]	adults 8 32 mg	adults 1 4 mg
rheumatic fever (acute)	in divided doses adults 16 20 mg children 8 10 mg	adults and children gradually reduce discontinue
vasomotor rhinitis	adults 8 16 mg children 4 8 mg	adults 1 4 mg children reduce discontinue
urticaria	adults [1] and children 12 20 mg for 5 days	
angioneurotic oedema	adults 8 16 mg	adults gradually reduce
rheumatoid arthritis	adults [1a] and children 4 12 mg	adults lowest adequate dose children individualized
lymphomatous diseases chronic lymphatic leukaemia	adults and children 32 60 mg	adults and children 2 24 mg
acute lymphatic leukaemia	children 1 mg/kg body weight	same as initial dosage
lupus erythematosus disseminated other collagen diseases	adults and children 20 32 mg	adults and children 4 20 mg

Condition	*Initial Daily Dosage*	*Maintenance Daily Dosage*
acute connective tissue diseases (acute rheumatic myocarditis)	adults 8 16 mg	adults 1 8 mg
uveitis	adults 24 32 mg	adults gradually reduce
psoriasis	adults 12 24 mg children 3 mg or more	adults and children gradually reduce

[1] Single daily doses have been effectively employed

[2] A single daily dosage regimen may be tried If response is not satisfactory daily dosage should be given in divided amounts If no response is observed within 7 days consideration should be given to the possibility of an erroneous diagnosis

For some chronic dermatoses an alternate day dosage regimen using doses equivalent to daily dosage may be effective *Severe pemphigus requires high initial doses even up to 100 mg daily in divided doses*

Potent systemic steroids are not recommended for mild uncomplicated psoriasis Psoriasis recurs when medication is discontinued and may be more severe due to rebound phenomenon

[4] *Appropriate antibiotic therapy must be given simultaneously*

Presentation

Scored tablets 1 mg Strips of 10 tablets and boxes of 10 strips of 10 s
4 mg Strips of 10 tablets and boxes of 10 strips of 10 s
8 mg Strips of 6 tablets and boxes of 8 strips of 6 s

Note Store at room temperature

KENACORT® INJECTION 10 mg — Parenteral Suspension

Triamcinolone Acetonide Aqueous Suspension

(NOT FOR INTRAVENOUS USE)

Kenacort Injection is a synthetic corticoid with marked anti inflammatory action It is available as a sterile aqueous suspension each ml providing 10 mg triamcinolone acetonide with sodium chloride for isotonicity 0 9% benzyl alcohol as a preservative 0 75% sodium carboxymethylcellulose and 0 04% polysorbate 80

Action and Uses The preparation is intended for intra articular intrasynovial or intrabursal injection in the treatment of the pain and inflammation of joints bursae and tendon sheaths and for intralesional (intradermal and sometimes subcutaneous) injection in the management of a variety of localized dermatoses

Intra articular The drug provides valuable local therapy of joint pain arising from such conditions as rheumatoid arthritis osteoarthritis tendinitis

synovitis bursitis and other conditions amenable to local corticosteroid injections It offers freedom from systemic action particularly when injections are given adjunctively in the management of the arthritides According to clinical reports the preparation has produced good to excellent results in the vast majority of patients

Relief of pain and swelling and greater freedom of movements are usually obtained within a few hours after injection amelioration of symptoms may be permanent or sustained over a period of one to several weeks Kenacort frequently provides substantial long lasting benefits where previously administered corticosteroid such as hydrocortisone or the prednisteroids afforded only partial or transient relief In processes the preparation s intended to supplement other conventional therapeutic measures Since intra articular administrations when given in the usual dosage range do not produce physiologic hormonal effects the drug is of particular value when systemic steroid therapy is contraindicated in these conditions For localized conditions such as traumatic arthritis or bursitis intra articular administration may be the sole therapy required Moreover side effects such as painful local reactions which have occurred with intra articular use of other corticosteroids have been rare following injection of triamcinolone acetonide

Intradermal Injection of the drug directly into localized lesions of many dermatologic conditions produces a relatively prompt involution and rapid relief of pruritus Intradermal administration is often effective where topical corticosteroid applications have failed and may produce prolonged remissions where topical steroids have effected only temporary relief Moreover this procedure avoids the systemic effects which may accompany oral or parenterally administered corticosteroids Clinical results obtained with this preparation recommend its use for the localized hypertrophic infiltrated inflammatory lesions of such conditions as lichen simplex chronicus (neurodermatitis) psoriatic plaques granuloma annulare lichen planus certain keloids and alopecia (areata and totalis)

Contraindications The use of corticosteroids is contraindicated in the presence of local or systemic viral infection tuberculosis of the skin or any active infection in or near joints or dermatologic lesions The preparation should not be used to alleviate joint pain arising from infectious states such as gonococcal or tuberculous arthritis

Warning Because it is a suspension the preparation should not be administered intravenously Strict aseptic technique is mandatory

Precautions Although therapy with Kenacort Injection will ameliorate symptoms it is in no sense a cure and the hormone has no effect on the cause of the inflammation Therefore this method of treatment does not obviate the need for the conventional measures usually employed *With intra articular administration the inadvertent injection of the suspension into the soft tissues surrounding a joint is not harmful but may lead to the occurrence of systemic effects and is the most common cause of failure to achieve the desired local results*

A marked increase in pain accompanied by local swelling further restriction of joint motion fever and malaise are suggestive of a septic arthritis If these complications should appear and the diagnosis of sepsis is confirmed antimicrobial therapy should be instituted immediately and

continued for 7 to 10 days after all evidence of infection has disappeared

Following intra articular steroid therapy patients should be specifically warned to avoid over use of joints in which symptomatic benefit has been obtained Negligence in this matter may permit an increase in joint deterioration that will more than offset the beneficial effects of the steroid

Unstable joints should not be injected Repeated intra articular injection may in some cases result in instability of the joint X ray follow up is suggested

Unlike other corticosteroids triamcinolone and its derivatives do not stimulate appetite during prolonged therapy *a liberal protein intake is essential* and administration of anabolic steroids may be useful for counteracting the tendency to gradual weight loss sometimes associated with negative nitrogen balance wasting and weakness of skeletal muscles

Since rare cases of anaphylactoid reacions following parenteral triamcinolone therapy have been reported appropriate precautions are advised

In females past menarche menstrual irregularities (amenorrhoea intermenstrual spotting or prolonged bleeding) can occur this possibility should be mentioned to the patient It should also be borne in mind that triamcinolone acetonide like other glucocorticoids may aggravate diabetes so that higher insulin dosage may become necessary or it may precipitate the manifestation of latent diabetes mellitus Corticosteroids are not recommended for patients with myasthenia gravis diverticulitis fresh intestinal anastomoses thrombophlebitis psychotic tendencies exanthematous diseases chronic nephritis metastatic carcinoma osteoporosis and history of peptic ulcer In the presence of any of these conditions the need for steroid therapy must be carefully weighed against the possible deleterious effects

As with other corticosteroids the possibility of other severe reactions should be considered If such reactions should occur appropriate corrective measures should be instituted and use of the drug discontinued

Side Effects Undesirable reactions following intra articular administration of the preparation have included transient pain occasional local irritation at the injection site and occasional brief increase in joint discomfort following intradermal administration transient local discomfort and local atrophy (which usually disappears unless the basic disease process is itself atrophic) have occurred

Since systemic absorption may occasionally occur with intra articular or other local administration patients should be watched closely for side effects associated with any corticosteroid therapy These include relative adrenocortical insufficiency (particularly in times of stress due to trauma surgery or severe illness) hyperglycaemia glycosuria aggravation or masking of infection osteoporosis (reversible only with difficulty) spontaneous fractures aseptic necrosis of the hip myopathy weakness activation and complication of peptic ulcer including perforation and haemorrhage acute pancreatitis ulcerative oesophagitis moon face buffalo hump abnormal fat deposits acne striae hirsutism flushing of the face sweating menstrual irregularities petechiae and purpura necrotizing angiitis growth suppression in children thromboembolism insomnia

psychic disturbances (particularly mild depression in contrast to the euphoria seen with other glucocorticoids) vertigo headache increased intracranial pressure papilloedema posterior subcapsular cataracts (occasionally requiring extraction) and rarely oedema hypertension syncopal episodes and anaphylactoid reactions

When adverse reactions do occur they are usually reversible and disappear when the hormone is discontinued

Administration and Dosage Shake the vial before use to insure a uniform suspension After withdrawal inject without delay to prevent settling in the syringe Careful technique should be employed to avoid the possibility of entering a blood vessel or of introducing infection

Intra articular Dosage depends on the size of the joint and the severity of symptoms Doses of 2 5 to 5 mg *for smaller joints* and 5 to 15 mg *for larger joints* have usually been sufficient to palliate symptoms Single injections for multiple joint involvement of up to a total of 20 mg or more have been given without incident

Dosage may be increased if initial results are inadequate or too transient A single injection frequently affords complete remission of symptoms However several injections may be needed for satisfactory relief Response to the preparation varies in duration For some patients remission of symptoms is permanent while others may require subsequent courses of therapy after periods of relief ranging from one week to several months The duration of temporary remission is often considerably improved following a series of injections and therapy should therefore be repeated on recurrence of symptoms and not at set intervals

The use of a local anaesthetic may often be desirable When a local anaesthetic is used with Kenacort Injection the anaesthetic package insert should be read with care and all the precautions connected with its use should be observed It should be injected into the surrounding soft tissues prior to the intra articular injection A small amount may also be instilled in the joint If an excessive amount of synovial fluid is present in the joint some but not all should be aspirated to aid in the relief of pain and to prevent undue dilution of the steroid Then the usual intra articular injection technique as described in standard textbooks should be followed For treatment of ganglia Kenacort Injection is injected directly into the cyst cavity In treating such conditions as tendinitis tenosynovitis or trigger finger care should be taken to ensure that the injection is made into the tendon sheath rather than into the tendon substance Conditions such as peritendinitis tennis elbow frozen shoulder rheumatoid nodules fibrositis and collateral ligament strains and sprains in the knee may be treated by infiltrating the preparation into the area of greatest tenderness

Intradermal The usual dose is 0 1 to 0 3 ml depending on the size of the lesion Whenever possible the volume injected at any site should be limited to 0 1 ml multiple sites (separated by one centimetre or more) may be used if more than this is required The multiple site method of administration will tend to minimize local tissue intolerance and the occurrence of atrophy The total volume administered at a session should probably not exceed 3 0 ml bearing in mind that the greater the total volume employed

the more corticosteroid becomes available for possible systemic absorption and subsequent systemic corticosteroid effects Administration may be repeated if necessary at weekly or less frequent intervals The preparation is injected directly into the lesion i e intradermally or sometimes subcutaneously For accuracy of dosage measurement and ease of administration it is preferable to employ a tuberculin syringe and a small bore needle (23 to 25 gauge) Ethyl chloride spray may be used to ease the discomfort of injection

Presentation 10 mg/ml 1 ml vials

Expiration date 24 months

KENACORT® INTRAMUSCULAR 40 mg — Parenteral Suspension

Triamcinolone Acetonide Aqueous Suspension

(NOT FOR INTRAVENOUS OR INTRADERMAL USE)

Kenacort Intramuscular is a sterile aqueous suspension providing a concentration of 40 mg triamcinolone acetonide per ml with sodium chloride for isotonicity 0 9% benzyl alcohol as a preservative 0 75% sodium carboxymethylcellulose and 0 04% polysorbate 80 Triamcinolone acetonide is a syntnetic corticosteroid with marked anti inflammatory action Kenacort Intramuscular is primarily intended for depot intramuscular administration in those allergies dermatoses and arthritides for other connective tissue disorders which are benefited by systemic corticosteroid therapy The preparation is also of value when local injection of a steroid is indicated for painful inflammatory conditions in joints bursae tendon sheaths or other localized areas particularly when a high steroid concentration in a small volume is desirable

Action and Uses Clinical reports on the systemic use of Kenacort Intramuscular have indicated that it offers a significant advantage over orally administered corticosteroid in that it need only be given intermittently even in chronic condition In sharp distinction to oral corticosteroids which usually are administered on a daily basis Kenacort Intramuscular has an extended duration of effect Following a single intramuscular dose of 40 to 80 mg amelioration of symptoms may be permanent or sustained over a period of several weeks

The intramuscular dosage of triamcinolone acetonide calculated on a per day basis is about 1 to 3 mg which is considerably less in many instances than the amount of steroid required with oral administration of triamcinolone In a study of triamcinolone preparations given intramuscularly for rheumatoid arthritis one investigator reported that in approximately 25% of his patients the intramuscular maintenance dose calculated on the basis of its daily equivalent was smaller than the oral dose which the patients had previously required Other clinical studies suggest that gastrointestinal side effects may be reduced when intramuscular steroid therapy is instituted in place of oral therapy

A significant number of patients particularly those with allergic disorders have experienced a prolonged remission of symptoms following intra muscular injection of triamcinolone acetonide

Studies indicate that following a single intramuscular dose of 60 to 100 mg of triamcinolone acetonide adrenal suppression occurs within 24 to 48 hours and then gradually returns to normal usually in 30 to 40 days This finding correlates closely with the extended duration of therapeutic action achieved with the drug

The local injection (such as intra articular) of Kenacort Intramuscular also has a prolonged effect in the majority of patients Improvement in movements and relief of pain and swelling which may be obtained within a few hours are frequently sustained over a period of several weeks and in self limited disorders may be permanent The freedom from systemic action following intra articular injection is a particularly desirable attribute especially when this mode of therapy is employed as an adjunct in the management of the arthritides Kenacort frequently provides substantial long lasting benefits where previously administered corticosteroids such as hydrocortisone or the prednisteroids afforded only partial or transient relief Moreover the side effects such as painful local reactions which have occurred with intra articular use of other corticosteroids have been rare following injection of triamcinolone acetonide

The intramuscular administration of Kenacort Intramuscular is indicated for systemic corticosteroid therapy in such conditions as allergic diseases dermatoses or generalized rheumatoid arthritis and other connective tis sue disorders Intramuscular administration is particularly valuable in such conditions when oral corticosteroid therapy is not feasible

Kenacort Intramuscular may also be given by intra articular or intrabursal administration and by injection into tendon sheaths or ganglia in the treatment of local inflammatory conditions when symptoms are severe enough to require higher-than-usual dosage This route of administration affords valuable local therapy of pain swelling stiffness arising from such conditions as traumatic or rheumatoid arthritis osteoarthritis synovitis bursitis and tendinitis The preparation should not be injected into trigger points unless injection is made into the musculature and not in overlying fat

In the management of generalized disease the intra articular injection or triamcinolone acetonide is intended to supplement other conventional therapeutic measures Since intra articular administration when given in the usual doses range generally does not produce physiologic hormonal effects the preparation is of particular value when systemic steroid therapy is contraindicated in these conditions For localized conditions such as traumatic arthritis or bursitis intra articular administration may be sole therapy required

Contraindications The use of corticosteroids is contraindicated in the presence of herpes simplex of the eye and in acute psychosis Although corticosteroids have been used in the treatment of chickenpox and in the treatment of tuberculosis these diseases are usually considered as contra indications The use of corticosteroids is contraindicated in the presence of local or systemic viral infection tuberculosis of the skin or any active

infection in or near joints or dermatologic lesions The preparation should not be used to alleviate joint pain arising from infectious states such as gonococcal or tuberculous arthritis

Warning Because it is a suspension the preparation should not be administered intravenously Strict aseptic technique is mandatory The preparation is not recommended for children under six years of age

Precautions

Following Administration by Any Route

Kenacort Intramuscular should be administered only with full knowledge of characteristic activity of and varied responses to adrenocortical hormones Like other potent corticosteroids triamcinolone acetonide should be used under close clinical supervision The increase in the weight oedema and hypertension which constitute the usual early unwanted steroid effects generally do not occur with triamcinolone acetonide thus patients must be carefully observed for less obvious signs Unlike other corticosteroids triamcinolone and its derivatives do not stimulate appetite during prolonged therapy *a liberal protein intake is essential* and administration of anabolic steroids may be useful for counteracting the tendency to gradual weight loss sometimes associated with negative nitrogen balance and wasting or weakness of skeletal muscles

Triamcinolone acetonide is not an agent of choice in the treatment of adrenocortical insufficiency When bacterial infections (local infections other than at the site of injection or systemic infections) are present therapy with triamcinolone acetonide is not recommended but may be employed with caution and only in conjunction with appropriate antibiotic or chemotherapeutic medication

Corticosteroids are not recommended for pregnant patients particularly in the first trimester except when the disease for which they are indicated is very severe In new borns of mothers who have received corticosteroid therapy the possible occurrence of hypoadrenalism should be borne in mind Triamcinolone acetonide like other glucocorticoids may aggravate diabetes so that higher insulin dosage may become necessary or it may precipitate the manifestation of latent diabetes mellitus

Corticosteroids are not recommended for patients with myasthenia gravis diverticulitis fresh intestinal anastomoses thrombophlebitis psychotic tendencies exanthematous diseases chronic nephritis metastatic carcinoma osteoporosis and history of peptic ulcer In the presence of any of these conditions the need for steroid therapy must be carefully weighed against possible deleterious effects In the case of peptic ulcer recurrence may be asymptomatic until perforation or haemorrhage occurs Therefore X-rays should be taken when therapy is prolonged or when there is any indication of gastric distress

As with other corticosteroids the possibility of other severe reactions should be considered If such reactions should occur appropriate corrective measures should be instituted and use of the drug discontinued

Continued supervision of the patient after termination of triamcinolone

acetonide therapy is essential since there may be a sudden reappearance of severe manifestations of the disease for which the patient was treated

Following Intramuscular Administration
Unless a deep intramuscular injection is given local atrophy is likely to occur (For recommendations on injection techniques see *Administration and Dosage*) Due to the significantly higher incidence of local atrophy when the material is injected into the deltoid area this injection site should be avoided in favour of the gluteal area Only very unusual circumstances would warrant injection into the deltoid area

Menstrual irregularities may occur and this possibility should be mentioned to female patients past menarche

Adrenal insufficiency is not likely to be a problem when intramuscular therapy is terminated but this possibility should be borne in mind Patients on long term systemic therapy with triamcinolone acetonide may require supportive corticosteroid therapy in times of stress (such as trauma surgery or severe illness) both during the treatment period and for a year afterwards

Following Intra articular Administration
Although therapy with Kenacort Intramuscular will ameliorate symptoms it is in no sense a cure as the hormone has no effect on the cause of inflammation Therefore this method of treatment does not obviate the need for the conventional measures usually employed *The inadvertent injection of the suspension into the soft tissues surrounding a joint is not harmful but may lead to the occurrence of systemic effects and is the most common cause of failure to achieve the desired local results*

Following intra articular steroid therapy patients should be specifically warned to avoid over use of joints in which symptomatic benefit has been obtained Negligence in this matter may permit an increase in joint deterioration that will more than offset the beneficial effects of the steroid

Unstable joints should not be injected Repeated intra articular injection may in some cases result in instability of the joint In selected cases particularly where repeated injections are given X ray follow up is suggested

An increase in joint discomfort has seldom occurred A marked increase in pain following intra articular injection accompanied by local swelling further restriction of joint movement fever and malaise may indicate a septic arthritis If the diagnosis of septic arthritis is confirmed administration of triamcinolone acetonide should be stopped and antimicrobial therapy should be instituted immediately and continued for 7 to 10 days after all evidence of infection has disappeared

Side Effects

Following Administration by Any Route
Since side effects due to systemic absorption may occur (even with local administration and particularly with doses of 40 mg or higher) patient should be watched closely for side effects associated with any corticosteroid therapy These include relative adrenocortical insufficiency (particularly in time of stress due to trauma surgery or severe illness or after

cessation of therapy with triamcinolone acetonide–see *Precautions*) hyperglycaemia glycosuria aggravation or masking of infection osteoporosis (reversible only with difficulty) spontaneous fractures aseptic necrosis of the hip myopathy weakness activation and complication of peptic ulcer including perforation and haemorrhage acute pancreatitis ulcerative oesophagitis moon face buffalo hump abnormal fat deposits acne striae hirsutism flushing of the face sweating menstrual irregularities (amenorrhoea intermenstrual spotting or prolonged bleeding) petechiae and purpura necrotizing angiitis growth suppression in children thromboembolism insomnia psychic disturbances (particularly mild depression in contrast to the euphoria seen with other corticosteroids) vertigo headache increased intracranial pressure papilloedema posterior subcapsular cataracts (occasionally requiring extraction) and rarely oedema hypertension syncopal episodes and anaphylactoid reactions

When adverse reactions do occur they are usually reversible and disappear when the hormone is discontinued

Following Intramuscular Administration
Severe pain has been reported in a few cases Abscess formation and local depigmentation have also occurred

Following Intra articular Administration
Undesirable reactions have included transient pain occasional local irritation at the injection site local depigmentation and occasional brief increase in joint discomfort

Administration and Dosage Shake the vial before use to ensure a uniform suspension After withdrawal inject without delay to prevent settling in the syringe Careful technique should be employed to avoid the possibility of entering a blood vessel or introducing infection

Systemic Dosage 60 mg is the suggested initial dose for adults and children over 12 injected deep into the gluteal muscle Subcutaneous fat atrophy may occur if care is not taken to inject the preparation intramuscularly Dosage is usually adjusted within the range of 40 to 80 mg depending upon patient response and duration of relief However some patients may be well controlled on dosage as low as 20 mg or less Patients with hay fever or pollen asthma who are not responding to pollen administration and other conventional therapy may obtain a remission of symptoms lasting throughout the pollen season after one injection of 40 to 100 mg

The suggested initial dose for children from 6 to 12 years of age is 40 mg although dosage depends more on the severity of symptoms than on age or weight There is insufficient clinical experience with Kenacort Intramuscular to recommend its use in children under 6 years of age

Since duration of effect is variable subsequent doses of Kenacort Intramuscular for adults and children should be given when signs and symptoms recur and not at set intervals

Systemic Administration For systemic therapy with Kenacort Intramuscular injection should be made deeply into the gluteal muscle to ensure intramuscular delivery (see *Precautions*) For adults a minimum needle

length of 1 ½ inches is recommended In obese patients a longer needle may be required Use alternate sites for subsequent injections

Local Dosage For intra articular or intrabursal administration and for injection into tendon sheaths o ganglia dosage of Kenacort Intramuscular is dependent on the severity of symptoms and on the size of the joint of other localized area to be treated For adults doses up to 10 mg for smaller areas and up to 40 mg for larger areas have usually been sufficient to alleviate symptoms

Single injections into several joints for multiple locus involvement up to a total of 80 mg have been given without undue reactions A single local injection of triamcinolone acetonide is frequently sufficient but several injections may be needed for adequate relief of symptoms Duration of relief is variable For some patients remission is permanent following 1 to 2 injections for others subsequent courses of therapy may be required after periods of relief ranging up to several months The duration of temporary remission is often considerably lengthened following subsequent injections Therapy should be repeated on recurrence of symptoms and not at set intervals

Local Administration With intra articular or intrabursal administration and with injection of Kenacort Intramuscular into tendon sheaths or ganglia the use of a local anaesthetic may often be desirable When a local anaesthetic is used its package insert should be read with care and all the precautions connected with its use should be observed It should be injected into the surrounding soft tissues prior to the local injection of the corticosteroid A small amount of the anaesthetic solution may also be instilled into the joint If an excessive amount of synovial fluid is present in the joint some but not all should be aspirated to aid in the relief of pain and to prevent undue dilution of the steroid The usual injection technique as described in standard textbooks should then be followed For treatment of ganglia Kenacort Intramuscular is injected directly into the cyst cavity In conditions such as tendinitis tenosynovitis or trigger finger care should be taken to ensure that the injection is made into the tendon sheath and not into the tendon substance Such conditions as peritendinitis tennis elbow frozen shoulder rheumatoid nodules fibrositis and collateral ligament strains and sprains in the knee may be treated by infiltrating Kenacort Intramuscular into the area of greatest tenderness

For other uses a more dilute form of triamcinolone acetonide is available

Presentation 40 mg/ml 1 ml vials

Expiration date 24 months

KENADERMA® Ointment

Triamcinolone Acetonide with Halquinol (Quixalin®)

Kanaderma combines the well-proven topical corticosteroid triamcinolone acetonide with halquinol (Quixalin)

Kenaderma contains

Triamcinolone acetonide	0 025%
Halquinol (Quixalin)	0 75%

Because corticosteroid therapy increases the risk to secondary infection particularly in skin lesions likely to be scratched Kenaderma is recommended for all dermatoses whether they are infected or not

Rationale With the increasing awareness of antibiotic sensitivity and the risk of producing antibiotic resistant organisms in patients being treated with topical preparations there is much to be said for the use of an efficient chemotherapeutic agent in dermatological preparations

Halquinol is such a chemotherapeutic agent with the additional benefit of a wider spectrum being active against all common skin pathogens including fungi and yeasts

Dermatologists are becoming increasingly aware of subclinical infection in the common skin diseases such as eczema Kenaderma with its powerful chemotherapeutic agent halquinol covers this risk of hidden infection The range of conditions which may be treated also includes intertrigo and pruritus ani where the antifungal activity of halquinol makes Kenaderma particularly suitable

Action Kenaderma provides rapid complete often prolonged relief of itching and burning in a wide variety of skin disorders Kenaderma also prevents or combats secondary skin infections due to bacteria and fungi

Indications Kenaderma is indicated for the treatment of inflammatory dermatoses where topical corticosteroids would normally be used

1 In infective conditions such as folliculitis and sycosis barbae the advantages of using Kenaderma are obvious with its antibacterial antifungal and anti-inflammatory properties

2 Eczemas as a group can be successfully treated with Kenaderma especially when the real problem of masked or subclinical infection which so commonly occurs is considered

Kenaderma is indicated in

- infantile eczema and atopic eczema
- napkin dermatitis
- seborrhoeic dermatitis
- varicose eczema
- contact dermatitis
- intertrigo
- anogenital pruritus

3 Fungus diseases of the skin including paronychia where there is a degree of inflammatory reaction may well benefit from the use of a potent corticosteroid combined with a powerful fungicide Kenaderma covers these aspects and has the added advantages of being active against yeast infections which are so commonly the cause of chronic paronychia

4 In chronic recalcitrant dermatoses where occlusive dressings are used in conjunction e g

(a) chronic eczema and pompholyx
(b) lichen planus
(c) lichen simplex

Advantages

- triamcinolone acetonide in Kenaderma is dramatically effective giving rapid complete and prolonged relief of itching burning and inflammation
- halquinol in Kenaderma is consistently effective against most of the skin pathogens both bacterial and fungal including antibiotic resistant staphylococci
- halquinol in Kenaderma is not an antibiotic and to date skin sensitization has not been reported
- halquinol in Kenaderma is more active *in vitro* than other halogenated derivatives of oxine

Side Effects Transient stinging may be experienced in a very small percentage of patients A yellowish discolouration of the skin may occur with Kenaderma and clothing especially cotton may also be stained with Kenaderma but this is easily washed out Sensitization has not yet been reported

Contraindications Kenaderma should not be used in the eye and care should be taken when applying the ointment near the eyes Kenaderma is not indicated for treating primary skin infections like boils infected wounds etc Kenaderma is not indicated in tuberculosis and viral skin disorders

Presentation Kenaderma is supplied in 5 g collapsible tubes

KENALOG S®

Lotion Ointment

Triamcinolone Acetonide with Neomycin
Gramicidin (Spectrocin®)

Kenalog S combines the potent *anti inflammatory anti allergic antipruritic* action of triamcinolone acetonide with the wide spectrum *antibiotic* action of Spectrocin It provides prompt complete often prolonged relief of itching burning inflamed skin lesions threatened or complicated by secondary bacterial infection

Each ml of Kenalog S Lotion supplies 1 0 mg (0 1%) triamcinolone acetonide 2 5 mg neomycin base (as sulphate) and 0 25 mg gramicidin

Kenalog S Ointment is available in two strengths Kenalog S 0 05% and Kenalog S 0 1%

Each gramme Kenalog S 0 05% Ointment supplies 0 5 mg (0 05%) triamcinolone acetonide 2 5 mg neomycin base (as sulphate) and 0 25 mg gramicidin

Each gramme Kenalog S 0 1% Ointment supplies 1 0 mg (0 1%) triam cinolone acetonide 2 5 mg neomycin base (as sulphate) and 0 25 mg gramicidin

- **TRIAMCINOLONE ACETONIDE** is clinically distinguished by its marked anti inflammatory anti allergic antipruritic effects It produces good to excellent therapeutic results in the vast majority of patients Paired com parison studies with 1 0% hydrocort sone and 0 5% prednisolone prepara tion have shown that triamcinolone acetonide in 0 1% concentration usually acts faster and produces more dramatic more consistent and more com plete therapeutic results Moreover triamcinolone acetonide is frequently effective in those instances where hydrocortisone and other topical steroids fail to bring about a good or complete therapeutic response

- **SPECTROCIN** combines the broad spectrum activities of two potent topical antibiotics neomycin and gramicidin The joint actions of these powerful anti infectives provide comprehensive antibacterial therapy against a wide range of gram positive and gram negative bacteria includ ing those responsible for most bacterial skin infections

Indications Kenalog S is indicated in the following conditions when threat ened or complicated by bacterial superinfection

- atopic dermatitis
- contact dermatitis
- eczematous dermatitis
- infectious eczematoid dermatitis
- neurodermatitis
- seborrhoeic dermatitis
- insect bites
- lichen simplex chronicus
- stasis dermatitis
- nummular eczema
- infantile eczema
- anogenital pruritus

and other dermatoses amenable to top cal corticosteroid antibiotic therapy

In exfoliative dermatitis and in localized eczematized lesions of psoriasis Kenalog S in conjunction with other indicated topical and/or systemic measures may be of value

Advantages

- four basic therapeutic effects–anti-inflammatory anti allergic antipruri tic antibacterial
- dramat cally effective–affords rapid complete often prolonged relief of itching burning and inflammation
- frequently effective in those instances where hydrocortisone and other topical corticosteroids fail to bring about a good or complete therapeutic response
- a potent antibacterial preparation–combats or prevents bacterial infec tion
- well tolerated–systemic toxicity has not been observed local intolerance to triamcinolone acetonide is rare sensitivity reactions following the use of neomycin sulphate and gramicidin are seldom encountered

Administration Apply to the affected areas 2 to 3 times daily

Undesirable Effects Triamcinolone acetonide is extremely well tolerated Systemic toxicity such as oedema and electrolyte imbalance have not been

observed Local intolerance to triamcinolone acetonide is rare – less than 1% in clinical studies of more than 2 000 patients Sensitivity reactions following the use of Spectrocin (neomycin gramicidin) are also seldom encountered

Presentation Kenalog S Lotion 0 1% 5 ml plastic squeeze bottles

Expiration date 18 months Store in a cool place

Kenalog S Ointment 0 05% 5 g tubes
Kenalog S Ointment 0 1% 2 5 g and 5 g tubes

Expiration date 36 months May be stored at room temperature

KENALOG S® NASAL DROPS — Drops

Triamcinolone Acetonide Neomycin Gramicidin (Spectrocin®) with Phenylephrine

Kenalog S Nasal Drops combines the potent anti inflammatory cortico steroid triamcinolone acetonide and the dependable antibiotics neomycin and gramicidin (Spectrocin) with the effective local vasoconstrictor phenyl ephrine for intranasal use in the management of inflammatory conditions involving the nasal passages and contiguous structures

Kenalog S Nasal Drops is available in a special plastic squeeze bottle designed to deliver a spray of approximately 0 1 ml per squeeze

Each ml of Kenalog S Nasal Drops provides

Triamcinolone acetonide	0 17 mg (0 017%)
Neomycin base (as neomycin sulphate)	3 5 mg
Gramicidin	0 05 mg
Phenylephrine	5 mg (0 5%)
in scented aqueous vehicle	

Action Triamcinolone acetonide aids in the reduction of capillary permeability and mucous membrane oedema by virtue of its anti inflammatory and anti allergic effects The resultant relief of nasal congestion with conse quent improvement in ease of breathing may be more prolonged than with the use of vasoconstrictors alone The concentration of triamcinolone ace tonide in the preparation is sufficient for good local activity and yet low enough to avoid systemic effects

The two potent antibiotics neomycin and gramicidin are active against a wide range of pathogenic bacteria Phenylephrine is one of the most com monly employed rapid-acting topical nasal vasoconstrictors By shrinking the local tissues it not only promotes easier breathing and better local drainage but also permits other therapeutic agents to gain more complete access to the mucous membranes of the nasal and paranasal passages

Advantages

- rapidly clears nasal blockage of inflammatory/allergic origin
- 3 way therapy–marked corticosteroid/decongestant/antibiotic benefits

–potent anti inflammatory effects of a corticosteroid triamcinolone acetonide

–dependable antimicrobial activities–neomycin and gramicidin are highly active against a wide range of pathogenic bacteria

–proved vasoconstrictor activity–phenylephrine permits other therapeutic agents to gain more complete access to mucous membranes of nasal and paranasal passages

Indications Kenalog S Nasal Drops is indicated most often as adjunctive therapy in the management of acute or chronic allergic or nonallergic inflammatory disease and in those infections caused by organisms susceptible to neomycin and gramicidin when the nasal passages and/or accessory nasal sinuses or other contiguous structures (eustachian tubes middle ear nasopharynx) are involved Other necessary measures may include environmental control desensitization procedures antihistamines systemic corticosteroids or antibiotics or other local procedures such as sinus irrigation or tubal insufflation Such common conditions as seasonal or perennial allergic rhinitis vasomotor rhinitis and infectious rhinitis may be expected to be benefited

Contraindications Although the likelihood is minimal of systemic steroid effects from the use of the nasal drops it should be borne in mind that corticosteroids are contraindicated in the presence of active peptic ulcer acute glomerulonephritis herpes simplex of the eye and infections that cannot be controlled with antibiotics Topical steroid preparations are contraindicated in tuberculous fungal and most viral lesions herpes simplex vaccinia and varicella particularly The preparation is also contraindicated in patients with a history of hypersensitivity to any of its components

Side Effects and Precautions Phenylephrine when used intranasally is not likely to cause systemic effects Sensitivity reaction to the antibiotics used is seldom a problem Kenalog S Nasal Drops is well tolerated and is not likely to cause any systemic toxicity such as oedema or electrolyte imbalance In a few patients the nasal spray may induce local discomfort such as a smarting sensation pruritus or a feeling of dryness Rebound congestion can be minimized by shorter period of use In case of resistant infections or if secondary infection due to non susceptible organisms appear Kenalog S Nasal Drops should be discontinued and/or other appropriate measures taken

Dosage The recommended dose for adults is 2 to 3 drops in each nostril 3 to 5 times a day For children (over six years) the dose is 1 to 2 drops in each nostril 3 to 5 times a day Kenalog S Nasal Drops is not recommended for children below six years

Administration Before using shake the bottle gently With the head upright place the tip in the nostril and squeeze the bottle once while inhaling gently Take out the tip from the nostril before releasing pressure Repeat for the other nostril

Presentation Kenalog S Nasal Drops is supplied in special plastic squeeze bottles of 10 ml

Expiration date 18 months

KENALOG-S® OPHTHALMIC OINTMENT — Ophthalmic Ointment

Triamcinolone Acetonide with
Neomycin Gramicidin (Spectrocin®)

Kenalog S Ophthalmic Ointment Triamcinolone acetonide with Neomycin Gramicidin (Spectrocin) ophthalmic ointment provides in each gramme 1 mg (0 1%) triamcinolone acetonide neomycin sulphate equivalent to 2 5 mg neomycin base and 0 25 mg gramicidin in Plastobase® Ophthalmic (Plasticized Hydrocarbon Gel) ointment base for ophthalmic and otic use

Action Triamcinolone acetonide is clinically distinguished by its prompt and marked topical anti inflammatory anti allergic and antipruritic effects When applied to the conjunctiva it suppresses inflammatory reactions involving the anterior segment of the eye inhibits vascularization and corneal scarring controls ocular exudation and relieves itching smarting and burning

Neomycin and gramicidin combine the broad spectrum activities of two potent topical antibiotics Neomycin is predominantly effective against staphylococci and gram-negative organisms gramicidin is included in the formulation chiefly for its activity against streptococci Together they provide comprehensive antibacterial therapy or prophylaxis against a wide range of gram-positive and gram negative organisms

The ointment vehicle affords prolonged contact between the therapeutic agents and ocular or otic lesions The ointment is particularly useful for night time application in ophthalmic conditions where its extended contact with affected tissue during the hours of sleep minimizes the need to wake the patient for administration of therapy

Kenalog S Ophthalmic Ointment is also suitably formulated for otic use It controls inflammatory reactions involving the external ear and canal reduces oedema relieves pain and itching inhibits exudation and prevents or controls infection due to susceptible organisms

dvantages

- specifically for ophthalmic and otic use
- provides marked *anti-inflammatory anti allergic antipruritic* and *anti bacterial* effects
- triamcinolone acetonide is the clinically superior corticosteroid – dermatologic effectiveness topically is 40 times greater than hydrocortisone 10 times greater than dexamethasone
- rapidly relieves itching redness smarting and burning in the eye medically and postoperatively
- effectively treats inflamed itching lesions of the external ear and auditory canal
- affords dependable broad spectrum antibiotic therapy and prophylaxis provides in neomycin and gramicidin greater antibacterial depth of activity
- avoids the problem of sensitization in any future systemic treatment of more serious infections

- maintains homogeneity – even at warm temperatures the base does not lose its suspending power

Indications Kenalog-S Ophthalmic Ointment is indicated for inflammatory conditions involving the anterior segment of the eye including nonpurulent blepharitis acute nonpurulent conjunctivitis iritis or iridocyclitis episcleritis superficial keratitis and corneal traumas such as abrasions and burns By virtue of the broad topical antibacterial spectrum provided by neomycin and gramicidin the ointment is particlarly useful in these inflammatory ocular conditions when bacterial infection threatens or is present It is also indicated prophylactically or therapeutically following various ophthalmic surgical procedures such as cataract extractions and strabismus corrections

The ointment is also indicated for various acute or chronic inflammatory conditions either infectious (bacterial) or noninfectious in origin involving external ear and auditory canal (otitis externa) e g seborrhoeic dermatitis and eczematous dermatitis

Contraindications Because the anti inflammatory effects of corticosteroids may mask the signs of an infection and cause it to spread the preparation is contraindicated for the lesions of acute herpes simplex vaccinia varicella and most other viral infections tuberculous or fungal infections of the eye or ear and acute purulent untreated conjunctivitis or blepharitis The preparation is also contraindicated in those persons known to be hypersensitive to any of its components

Adverse Reactions and Precautions The preparation is generally well tolerated Local irritation may occur in some patients It is usually manifested as a transient burning sensation following instillation in the eye or ear

Prolonged conjunctival application of topical corticosteroids may cause increased intraocular pressure in certain individuals It is advisable that intraocular pressure be checked frequently when the preparation is so used

In diseases causing thinning of the cornea perforation has occurred with the use of topical corticosteroids

As with any antibiotic preparation prolonged use may result in overgrowth of non-susceptible organisms including fungi Constant observation of the patient is essential Should superinfection occur the preparation should be discontinued and/or appropriate therapy instituted

Dosage and Administration Eye A 1/2 inch column of ointment should be applied to each affected eyelid two or three times daily Since some ocular inflammations are prone to relapse it is advisable to discontinue dosage gradually maintaining close observation of the patient

Patients should be instructed to take appropriate measures to avoid contaminating the applicator when applying the preparation

If blurring of vision is to be avoided during working hours it may be advisable to administer a solution formulation in the daytime reserving the ointment for use at bedtime only

Ear If possible clean the auditory canal thoroughly A thin film of the ointment should be applied to the affected ear two or three times daily A

cotton tipped applicator may be used if desired

Presentation Tubes of 2 5 g with ophthalmic tip

Expiration date 24 months May be stored at room temperature

KENAMINA® Tablets

Triamcinolone and Carbinoxamine Maleate

Kenamina is a combination of triamcinolone – a potent corticosteroid with anti inflammatory antirheumatic and anti allergic actions and carbinoxa mine maleate a widely used effective antihistamine Each Kenamina Tab let contains 1 25 mg triamcinolone and 2 0 mg carbinoxamine maleate

Action Kenamina provides specific and effective treatment of allergic pruritic disorders The combination of triamcinolone and carbinoxamine maleate in which each component supplements the specific therapeutic action of the other provides optimal therapeutic benefits with smaller effective doses of the steroid than would have been required with corticosteroid therapy alone thus reducing the problem of side effects Kenamina is therefore especially suitable for long term therapy

Indications Kenamina is indicated for those allergic conditions in which anti histaminic and anti inflammatory actions are desirabe These include aller gic dermatoses urticaria angioneurotic oedema pruritus hay fever vaso motor rhinitis allergic conjunctivitis drug and serum reactions and certain cases of bronchial asthma

Advantages In a sigle preparation Kenamina provides

- anti inflammatory activity of triamcinolone (Kenacort)
- antihistamine action of carbinoxamine maleate
- antipruritic as well as anti allergic effect of both
- risk of side effects is considerably less with Kenamina than that produced by therapeutically equivalent dosages of either component alone

Dosage The usual initial dose is one to two tablets orally The dosage can be repeated at six hourly intervals This dose should be adjusted to the indivi dual requirements of the patient with reduction to minimum maintenance level as improvement is obtained and discontinued as necessary

Contraindications As with other corticosteroids triamcinolone should not be administered to patients with tuberculosis active peptic ulcer herpes sim plex of the eye exanthematous eruptions or agitated psychotic states

Precautions Since drowsiness may occur while on this medication extra ca e should be exercised in prescribing this to those who drive motor vehicles and those operating machinery The physician must calculate the antici pated clinical improvement against the possibility of untoward effects before using this product in patients with cardiac failure severe hyper tension diabetes mellitus renal insufficiency osteoporosis or in patients with marked emotional instability and psychotic tendencies Since triamci

nolone may mask many signs of infection the drug should not be administered until a diagnosis has been arrived at Therapy should be discontinued if untoward effects are observed

Presentation Strip of 10 tablets and boxes of 10 strips of 10 s

LIMCEE* 500 mg **Chewable Tablets**

Vitamin C Chewable Tablets

Limcee is a chewable tablet containing Vitamin C 500 mg Vitamin C is concerned with the formation and maintenance of intercellular supporting structures like collagen cartilage dentine bone matrix etc it is also related to the synthesis of intercellular cement of the capillary endothelium

Vitamin C is used for the treatment of ascorbic acid deficiency especially scurvy a bleeding disorder which occurs rather infrequently in infants and adults (e g bottle fed infants and elderly people) Vitamin C functions in a number of biochemical reactions mostly involving oxidation Ascorbic acid improves resistance to infections Microbial diseases have long been recognized to precipitate scurvy in individuals on border line intakes of this vitamin Delayed healing of wounds postoperative breakdown of incisions and delayed union of fractures may sometimes be at least partly the result of unrecognized but severe ascorbic acid deficiency Vitamin C plays an essential role in the medical care in patients with thermal burns for they too develop ascorbic acid deficiency

Vitamin C is essential for the protection of folic acid reductase which converts folic acid to folinic acid It may participate in the release of free folic acid from its conjugates in food and it facilitates the absorption of iron It stimulates maturation of developing blood cells in bone marrow

Indications Limcee is indicated in the treatment of Vitamin C deficiency Limcee is also indicated for the prevention or treatment of scurvy Given before and after surgery Limcee aids in the healing of wounds in patients with clinical or subclinical Vitamin C deficiency

Dosage One or more tablets daily as directed by the physician

Presentation Strips of 10 tablets and boxes of 10 strips of 10 s

Expiration date 24 months

LIVER INJECTION CRUDE **Parenteral Solution**

Liver Injection Crude is a sterile aqueous solution of liver fraction containing the anti anaemia principle preserved with 0 5 per cent phenol It is a solution for intramuscular injection available in 10 ml vials Each ml contains Vitamin B_{12} activity equivalent to 2 mcg of cyanocobalamin It is usually well tolerated and offers the advantage of being low in total solids

and at the same time comprising vitamins of B Complex in natural form and proportion

Indications Deficiency of anti anaemic principle derived from liver appears to be common to all macrocytic anaemias Liver Injection Crude is effective in the treatment of all macrocytic anaemias and when combined with other therapy it is a valuable adjunct in the management of patients intolerant to treatment with arsenicals and other heavy metal drugs and in the management of anaemias associated with pellagra sprue celiac disease atrophic gastritis cirrhosis of the liver ulcerative colitis radiation illness hyperemesis gravidarum shock incident to severe thermal burns and lupus erythematosus It provides a source of the unsynthesized members of vitamin B Complex for malnourished patients

Dosage and Administration Liver Injection Crude is given by deep intramuscular injection into the buttocks It is desirable to administer liver extract in excess of basic requirements in order to maintain a normal blood level and store reserve supply in the body The clinical condition of the individual and the results of blood examinations are the criteria used to determine the adequacy of dosage employed Dosage requirements vary from patient to patient and even in the same patient according to the stage of the disease

As a routine 2 ml daily until blood count is restored to normal will serve for mild cases of anaemia Larger doses are generally required in markedly anaemic states sprue pellagra and other nutritional deficiencies characterized by intestinal manifestations Administration of 5 to 7 5 ml at appropriate intervals is recommended

Therapeutic response to Liver Injection is best achieved with a well balanced diet with emphasis on proteins vitamins and minerals

Presentation Vials of 10 ml

Note Should be stored in a cool place and protected from light

Expiration date 24 months

MAGNOMINT®

Magma

Mint-Flavoured Milk of Magnesia

Magnomint an effective antacid and a mild laxative is a smooth creamy and homogenized milk of magnesia containing sodium citrate saccharin and the special homogenizer carageenin It is distinguished by its deliciously different mint flavour

Advantages

- pleasant tasting – leaves no chalky gritty aftertaste
- made by a special homogenizing process which ensures a smoother creamier easy-to take preparation – less likely to settle on standing
- as an antacid – usually effective in a matter of minutes
- as a laxative – relieves mild constipation

Indications Antacid mild laxative sweetens the breath

Precautions Do not use any laxative when abdominal pain nausea or vomiting are present Frequent or prolonged use may result in dependence on laxatives

Dosage Antacid – Adults 1 to 4 teaspoonfuls in ½ a glass of water one or two hours after a meal or upon retiring Children ½ to 1 teaspoonful

Laxative – Adults 2 to 4 tablespoonfuls in ½ a glass of water preferably an hour before breakfast Children ½ to 2 tablespoonfuls Infants 1 teaspoonful may be added to the morning feeding

Presentation Magnomint bottles of 120 ml

Note Shake well before using Keep closed avoid freezing

MARCAIN§ 1% HYPERBARIC

Parenteral Solution

Bupivacaine Hydrochloride

(FOR SPINAL ANAESTHESIA)

Marcain 1% Hyperbaric (Bupivacaine Hydrochloride) is a local anaesthetic agent with long duration of action

Marcain Hyperbaric is a special 1% solution of high specific gravity This hyperbaric solution in addition to 1% Marcain contains 10 5% dextrose and thus has a specific gravity between 1 035 to 1 04

Action Marcain stabilizes the neuronal membrane and prevents the initiation and transmission of nerve impulses thereby affecting local anaesthetic action

Marcain is about four times more potent than lidocaine The local anaesthetic action of Marcain 1% is therefore equivalent to lidocaine 4% The onset of action is very rapid and is comparable to other local anaesthetic agents However Marcain has distinct advantages over other local anaesthetic agents because it provides duration of anaesthesia significantly longer than other available local anaesthetic agents 1-2 ml of Marcain 1% Hyperbaric provides profound anaesthesia lasting for several hours (average 3 hours and more) It has also been noted that there is a period of analgesia that persists after the return of sensation and during this time the need of strong analgesic is reduced Marcain 1% Hyperbaric is non-irritant and no tissue damage or tissue irritation has been observed After injection peak blood levels are reached between 30 to 45 minutes followed by a decline to insignificant levels in 3 to 6 hours Marcain is metabolized in liver and excreted through the kidneys

Indications Marcain 1% Hyperbaric is indicated for inducing spinal anaesthesia Most of the surgical procedures where spinal anaesthesia can be used are similar to those of epidural anaesthesia The prominent features of spinal anaesthesia are

a) A bloodless field of operation
b) When a contracted bowel is required

c) Old arteriosclerotic and diabetic patients
d) Abdominal operations in fat patients

Advantages

Marcain 1% Hyperbaric for spinal anaesthesia provides a rapid and pro longed regional anaesthesia as compared with mepivacaine and ligno caine thus avoiding the need for combination with vasoconstrictor drugs

Like epidural anaesthesia sensory analgesia continues for a much longer time than other available local anaesthetics reducing an early post operative requirement of analgesics

Adequate motor and sensory blockade is achieved thus obviating the use of muscle relaxants

Marcain 1% Hyperbaric is stable and needs no special precautions for storage

Marcain 1% Hyperbaric is safe and has minimum side effects toxic reactions and neurological complications

Contraindications Marcain 1% Hyperbaric is contraindicated in the following conditions which preclude its usage in spinal anaesthesia

1 Severe haemorrhage shock or heart block
2 Local infection at the site of proposed puncture
3 Sept caemia
4 Known sensitivity to the anaesthetic agent
5 Pre existing neurological disease such as poliomyelitis pernicious an aemia paralysis from nerve injuries and syphilis
6 Disturbance in blood morphology and/or anticoagulant therapy In these conditions trauma to a blood vessel during needle puncture may result in uncontrollable haemorrhage into the epidural or subarachnoid space Also profuse haemorrhage into the soft tissue may occur
7 Extremes of age
8 Chronic backache and pre operative headache
9 Arithritis or spinal deformity
10 Technical problems (persitent paraesthesia persistent bloody tap)
11 Psychotic or unco operative patients
12 Tuberculosis of lumbar spine

Precautions

(a) Care should be taken to avoid intravascular administration

(b) The safety of Marcain in pregnancy with respect to adverse effects on foetal development has not been established Therefore it is better to avoid the use of Marcain during early pregnancy However this does not exclude the use of Marcain at term for obstetrical analgesia No adverse effects on foetus course of labour or delivery have been observed when Marcain was used for obstetrical analgesia

(c) As with the use of all local anaesthetic agents the patient should be kept under close supervision and resuscitative equipment and drugs should be available

(d) The lowest dose that produces effective anaesthesia should be used Acutely ill debilitated and elderly patients should be given a reduced dose

(e) Extreme precautions must be employed for the usage of Marcain as spinal anaesthesia in patients with existing hypertension or hypoten sion

Adverse Reactions Marcain when used within therapeutic dosage and with careful and correct technique is absolutely safe without any significant adverse effects Reactions to Marcain are characteristic of those asso ciated with other local anaesthetics belonging to amide type and occur when excessive plasma levels are reached which may be due to over dosage invadvertent intravascular injection or slow metabolic degradation Excessive plasma levels cause systemic reactions involving central nervous system and cardiovascular system

The CNS effects are characterized by excitation or depression The mani festations may be nervousness dizziness blurred vision or tremors follow ed by drowsiness convulsions unconsciousness and possibly respiratory arrest Other CNS effects may be nausea vomiting chills constriction of pupil or tinnitus The cardiovascular manifestation of excessive plasma levels may be depression of myocardium hypotension and cardiac arrest

Allergic reactions which may be due to hypersensitivity idiosyncrasy of diminished tolerance are urticaria oedema and other manifestations of allergy

Reactions following spinal anaesthesia may man fest as

Post anaesthetic Headache – This can be minimized by use of small calibre needles (24 to 26 gauge) specially designed to prevent spinal fluid leakage and by keeping patient flat on the back without a pillow for appropriate period after delivery or operation

Nausea and Vomiting – These may result from psychic causes fall in blood pressure intra abdominal manipulation or concomitant medication

Palsies – Nerve palsies invloving extra ocular muscles legs vesical and anal sphincters have occasionally been reported These usually are tran sient and clear completely but in rare instances a permanent residual has been reported

Meningitis Myelitis – Careful selection of patients use of strictest aseptic techniques and scrupulous care to avoid injury to meninges and cord during anaesthetic drug injection should prevent infections and traumatic complications almost entirely Instances of aseptic meningitis or myelitis have occurred occasionally with permanent residual and fatal termination Aseptic meningitis or myelitis also have been reported in rare instances following diagnostic lumbar puncture without spinal anaesthesia following various operations for which spinal anaesthesia was not used and spinal tap was done and following pregnancy and delivery without use of spinal anaesthesia or spinal tap Meningismus also has been reported evidently without infection and usually clears promptly

Treatment of Adverse Reactions Toxic effects of Marcain require symptoma tic treatment The physician should be prepared to maintain patent airways

and to support ventilation with oxygen or control respiration as required Supportive treatment of cardiovascular system includes intravenous fluids and appropriate vasopressor Convulsions may be controlled with oxygen and intravenous administration of ultrashort acting barbiturate such as thiopental or a short acting barbiturate (e g secobarbital or pentobarbital) or diazepam

Dosage and Administration Spinal anaesthesia with Marcain 1% Hyperbaric may be induced in the right or left recumbent or sitting position Since this is a hyperbaric solution the anaesthetic will tend to move in the direction in which the table is tilted After the desired level of anaesthesia is obtained and the anaesthetic has become fixed usually in 5 10 minutes the patient may be positioned according to the requirement of surgeon or obstetrician The injection should be made slowly Consult standard textbooks for specific techniques and precautions for spinal anaesthetic procedures The dose of Marcain 1% Hyperbaric varies depending upon the type of surgical procedure and level of anaesthesia required In all cases the smaller dose that will produce the desired result should be given However in most of the cases the recommended dose is usually 1 to 2 ml (10 – 20 mg)

Presentation Ampoules of 2 ml (10 mg/ml)

Note Marcain 1% Hyperbaric should be stored in a cool place

Expiration date 24 months

MARCAIN[§] 0 5% — Parenteral Solution

Bupivacaine Hydrochloride

(FOR LOCAL ANAESTHESIA)

Marcain (Bupivacaine Hydrochloride) is the hydrochloride of 1 n butyl DL-piperidine 2 carboxylic acid 2 6 dimethylanilide

Marcain (Bupivacaine Hydrochloride) is a local anaesthetic agent with long duration of action Marcain is available in a concentration of 0 5% in sterile isotonic solution

Action The principal action of Marcain is to block the initiation and transmission of nerve impulses thereby producing local anaesthetic effects

Marcain is a local anaesthetic with a sufficiently long duration of motor and sensory anaesthesia to allow extended operations The specific feature of Marcain is to provide sensory analgesia which outlasts motor paralysis by 100 300% thus creating optimum conditions for a pain-free post-operative course

Marcain has distinct advantage over other local anaesthetic agents because it provides a duration of anaesthesia significantly longer than other available local anaesthetic agents The duration of local anaesthesia with Marcain may last for several hours (average 3 hours and more) It has also been noted that there is a period of analgesia that persists after the return of sensation and during this time the need for a strong analgesic is reduced

The need for combining Marcain with adrenaline or other vasoconstrictor agents is obviated since Marcain has a long duration anaesthetic effect

After injection peak blood levels are reached between 30 to 45 minutes followed by a decline to insignificant levels in 3 to 6 hours Marcain is metabolized in liver and excreted through the kidneys

Marcain is excreted unchanged in the urine to about 6% while the N-debutylated derivative amounts to 5% There are also indications that glucuronide conjugates of hydroxylated Marcain are excreted in human urine

Indications Local anaesthesia in many cases is the method for pain relief that interferes least with the patient s vital functions particularly in patients with an already decreased functional respiratory and circulatory capacity preoperatively where avoiding general anaesthesia is important

In accident cases the risk for aspiration of gastric contents may also prevent the use of general anaesthesia

Marcain in general is recommended for production of local or regional anaesthesia by infiltration techniques such as peripheral nerve block infiltration sympathetic block caudal or epidural block

Numerous clinical studies confirm the potency and long duration of action of Marcain in a variety of anaesthetic procedures

EPIDURAL ANAESTHESIA

(a) General Surgery Epidural anaesthesia can be given with single dose technique and is suitable for all surgery below the umbilical level for example appendectomy prostatectomy haemorrhoidectomy anal operations transurethral manipulations lower limb amputations paralytic ileus in absence of peritonitis and repair of hernia etc Marcain 0 5% gives motor anaesthesia up to 4 hours and sensory analgesia 4-7 hours which is very advantageous in the relief of post-operative pain It has also been reported that epidural anaesthesia decreases blood loss in prostatectomies

(b) Obstetrical Analgesia Epidural anaesthesia is a method giving effective pain relief during the first and second stages of labour combined with full patient s co operation By means of continuous techniques pain relief can be maintained during the whole delivery and also afterwards for example to abolish pain from vaginal repair work Low doses of Marcain 0 25% 5-10 ml (Marcain 0 5% diluted with equal volume of saline) starting with the patient in Trendelenburg position selectively blocks uterine pain leaving perineal nerve impulses unaffected Second stage pain is controlled by giving if necessary another 10 ml 0 25% Marcain with the patient in a sitting position When used with adrenaline Marcain was found to be safe as compared to mepivacaine or lignocaine with adrenaline The risks to recipient or to the foetus if they exist are less with Marcain than with lignocaine or mepivacaine Moreover it has also been suggested that addition of adrenaline may inhibit the force of uterine contractions Thus Marcain 0 5% plain will provide added safety to the recipient as well as the foetus

(c) Gynaecological Operations The choice of using Marcain 0 5% for epi dural anaesthesia i n gynaecological conditions would vary from patient to patient and the total duration of time expected to complete the surgical procedure Nevertheless because of the long duration of action of Marcain certain operat ons like myomectomy hysterectomy repair of vesicovag nal fistula rectovaginal fistula etc can be undertaken

(d) Relief of Pain Pain in general (and post operative in particular) presents a problem to all hospita's This is reflected by the number of agents used to alleviate pain Local anaesthesia is becoming increasingly popular as an efficient way of fighting pain without simultaneous respiratory depression or side effects

Marcain 0 25% is the drug of choice because it gives a pain free interva' of 6 8 hours when employed for single shot epidural anaesthesia In conti nuous epidural anaesthesia administration can be extended for several days Tach,phylaxis may occur but is less pronounced than with other local anaesthetics

CAUDAL BLOCK

A rather prolonged period of post operative analgesia accompanied by preganglionic sympathetic blockade is particularly apparen after caudal anaesthesia induced with Marcain This has definite advantages after hae morrhoidectomies and in the presence of vascular spasm in the legs secondary to trauma or surgery There is also a reduction in the need for post operative narcotics

The dosage for surgery is usually 20 30 ml Marcain 0 5% which also gives post operative freedom from wound pain for 6 8 hours Whereas muscle relaxation and motor blockade can be expected for 3 4 hours Marcain 0 25% in a volume of 15 20 25 ml gives sufficient analgesia for obstetric purpose duration 3 4 hours by single dose technique Continuous caudal block by means of a catheter is also of proven value

BRACHIAL PLEXUS BLOCK

Accidents involving hand and arm injuries generally need immediate atten tion after arrival in hospital General anaesthesia may in such cases be complicated by aspiration of stomach contents The analgesic method of choice here is brachial plexus block permitting surgery on the hand and arm With the axillary approach the risk of haemothorax is avoided

Duration ranging from 5 10 hours are obtained when 15 30 ml of Marcain 0 5% is administered Complete anaesthesia is achieved in about 20 min utes

INTERCOSTAL BLOCK

The post-operative analgesia after thorax and gall bladder operations is of considerable importance for a complication free recovery and rapid mobili zation of the patient Particularly in intercostal blocks Marcain has proved its superiority by giving anaesthesia for 10 16 hours Dosage ranges from 10 25 mg per segment corresponding to 4-8 ml Marcain 0 25% or 3 5 ml Marcain 0 5%

BLOCK OF SCIATIC AND FEMORAL NERVES

Combined sciatic and femoral blocks are of practical value in providing safe analgesia for surgery and in the treatment of pain in the lower limb The blocks are easy to perform and have a low failure rate Marcain 0 25% is suitable in a dose of 15 25 ml for a sciatic block and 10 15 20 ml for femoral block Duration between 6 and 15 hours can be expected

PARACERVICAL BLOCK

Paracervical block (PCB) is a widely used form of anaesthesia during child birth because of the simple technique A total dose of 50 mg Marcain should not be exceeded for PCB as the effect of higher doses on the foetus can be harmful Pre eclampsia toxaemia prematurity postmaturity diabetes vaginal infections abnormal foetal presentations placental insufficieny or suspected intrauterine hypoxia are contraindications to the use of PCB

Pudendal anaesthesia is used to complement paracervical block and covers the second and third stage of delivery

INFILTRATION ANAESTHESIA

Infiltration of tender nodules and subscapsular injections have been reported to give pain relief for 4 6 hours In addition infiltration anaesthesia with Marcain can also be used for numerous minor surgical parocedures like the removal of lipoma ganglion dermoid and sebaceous cysts and removal of foreign bodies

Advantages

- Marcain is safe when administered by any of the above mentioned techniques There is no special toxicity attached to Marcain *per se*
- The onset of analgesia and the intensity of block is almost the same as with other local anaesthetics
- Marcain has a prolonged duration of action usually lasting 4 to 6 hours The need for narcotic analgesics is further delayed by 2 to 4 hours This prolonged effect is not produced by available local anaesthetics with or without adrenaline
- Marcain solution is stable and poses no special problems for sterilization and storage

Contra ndications Marcain is contraindicated in patients with known history of hypersensitivity to local anaesthetics belonging to the amide group Its use should also be avoided in patients who have inflammation and/or sepsis in the proposed region of injection Marcain like other local anaesthetic agents should not be used in cases of severe shock and heart block Marcain is not recommended for children younger than 12 years

Precautions As is found with similar other anaesthetic agents the following precautions should be kept in mind

1 Care should be taken to avoid intravascular administration

2 No adverse effects on foetus course of labour or delivery have been observed when Marcain was used for obstetrical analgesia However it is better to avoid the usage of Marcain during early pregnancy

3 As with the use of all local anaesthetic agents the patients should be kept under close supervision and resuscitative equipment and drugs should be available

4 The lowest dose that produces effective anaesthesia should be used Acutely ill debilitated and elderly patients should be given a reduced dose

5 Extreme precautions must be employed for the usage of Marcain as epidural or caudal anaesthesia in patients with existing neurological disease septicaemia severe hypertension and spinal deformities

6 When used as paracervical block foetal bradycardia may follow Use caution and monitor foetal heart

Adverse Effects Marcain when used within therapeutic dosage and with careful and correct technique is virtually safe without any significant adverse effects Reactions to Marcain are characteristic of those associated with other local anaesthetics belonging to amide type

The CNS effects are characterized by excitation or depression The manifestations may be nervousness dizziness blurred vision or tremors followed by drowsiness convulsions unconsciousness and possible respiratory arrest Other CNS effects may be nausea vomiting chills constriction of pupil or tinnitus The cardiovascular manifestations of excessive plasma levels may be depression of myocardium hypotension and cardiac arrest

Allergic reactions which may be due to hypersensitivity idiosyncrasy or diminished tolerance are urticaria oedema and other manifestations of allergy

Reactions following epidural or caudal anaesthesia may manifest as high or total spinal block hypotension urinary retention faecal incontinence headaches and backache

Treatment of Adverse Reactions Toxic effects of Marcain require symptomatic treatment The physician should be prepared to maintain patent airways and support ventilation with oxygen or control respiration as required Supportive treatment of cardiovascular system includes intravenous fluids and appropriate vasopressor agents

Convulsions may be controlled with oxygen and intravenous administration of ultrashort acting barbiturate such as thiopental or a short-acting barbiturate (e g secobarbital or pentobarbital) or diazepam

Dosage and Administration As with all local anaesthetics the dosage of Marcain varies and depends upon the area to be anaesthetized the vascularity of the tissue the number of neuronal segments to be blocked individual tolerance and the technique of anaesthesia

The lowest dose needed to provide effective anaesthesia should be used In recommended dosage Marcain produces complete sensory block and also motor blockade with concentrations of 0 5% and above Sometimes

the muscle relaxation with 0 5% may not be adequate The following table presents the recommended doses of Marcain fo different procedures

Type of Block	Concentration	ml	Each dose (mg)
Local Infiltration	0 5%	Up to max	Up to max
Brachial Plexus	0 5%	15 30	75 150
Intercostal Nerve Block	0 5%	3 5	15 20 (for each nerve)
Trigeminal Block	0 5%	0 5 4	2 5 20
Epidural	0 5%	10 20	50 100
Caudal	0 5%	15 30	75 150
Sympathetic Block	0 5%	10 25	50 125

The maximum recommended dose required for a period of 6 hours is 2 mg/kg which is present in 25 30 ml of 0 5% solution for an adult weighing 65 70 kg

Presentation Vials of 10 ml and 20 ml (5 mg/ml)

Note May be stored at room temperature

Expiration date 24 months

MYCOSTATIN® OINTMENT

Ointment

Nystatin Ointment

Mycostatin is Nystatin an antibiotic with antifungal activity against a wide variety of yeasts and yeast like fungi Produced by a strain of *Streptomyces nourse*i Mycostatin is the first well tolerated antifungal antibiotic of dependable efficacy for the treatment of cutaneous oral and intestinal in fections caused by *Candida* (Monilia) *albicans*

Mycostatin is available for topical administration as ointment Mycostatin Ointment Nystatin in Plastobase is supplied in 10 g tubes providing 100 000 units nystatin per g of Plastobase® (Plasticized Hydrocarbon Gel) an emollient and protective vehicle

Mycostatin is well accepted by patients It does not stain skin or mucous membrane and provides a simple convenient means of treating cutaneous moniliasis

Action In concentrations of 2 0 units/ml or more Mycostat n is fungistatic *in vitro* against a variety of yeasts and yeast like fungi including the principal fungi pathogenic to man No appreciable activity is exhibited against bac teria

Mycostatin provides specific therapy for all localized forms of moniliasis Symptomatic relief is rapid often occur ing with n 24 to 72 hours after the initiation of treatment Cure is effected both clinically and mycologically in most cases of localized moniliasis

Advantages

- specific therapy
- virtually nontoxic and nonsensitizing
- rapid relief of symptoms
- no development of resistance in clinical practice
- enthusiastic patient acceptance

Indications Mycostatin Ointment is indicated in the treatment of cutaneous mycotic infections caused by *Candida* (Monilia) *albicans* If this organism is the primary cause of infection such dermatologic conditions as athlete foot (dermatophytosis) perleche paronychia intertrigo diaper rash and other cutaneous lesions can be expected to respond Mycostatin Ointment is also indicated in conjunction with Mycostatin Oral Tablets in the local treatment of chronic or resistant vaginal or cutaneous moniliasis especially when autoreinfection from the intestinal tract is a possibility

Administration and Dosage Mycostatin Ointment should be applied liberally to affected areas twice daily or as indicated until healing is complete

Side Effects Mycostatin is virtually nontoxic and nonsensitizing and well tolera ted by all age groups including debilitated infants even on prolonged ad ministration If irritation on topical application should occur discontinue medication

Presentation Tubes of 10 g

Expiration date 36 months May be stored at room temperature

MYCOSTATIN® ORAL TABLETS — Tablets

Nystatin Tablets

Mycostatin is Nystatin an antibiotic with antifungal activity against a wide variety of yeasts and yeast like fungi Produced by a strain of *Streptomyces noursei* Mycostatin is the first well tolerated antifungal antibiotic of dependable efficacy for the treatment of oral cutaneous and intestinal infections caused by *Candida* (Monilia) *albicans*

Mycostatin is available for oral administration in coated tablets containing 500 000 units nystatin

Action Mycostatin has been found to inhibit the growth of yeast like flora in the intestinal tract In concentrations of 2 0 units/ml or more Mycostatin is fungistatic *in vitro* against a variety of yeast like fungi including the princi pal fungi pathogenic to man The antibiotic exhibits no appreciable activity against bacteria

Following oral administration Mycostatin is absorbed sparingly No detect able blood levels are obtained when the antibiotic is given in the recom-

mended therapeutic and prophylactic doses and only traces of Mycostatin are found in the plasma following oral administration of considerably larger doses Most of the unabsorbed Mycostatin is passed unchanged in the stool

Advantages

- specific therapy
- virtually nontoxic and nonsensitizing
- rapid relief of symptoms
- no development of resistance in clinical practice
- enthusiastic patient acceptance

Indications Mycostatin for oral use is intended for the prevention and treatment of infections caused by *Candida* (Monilia) *albicans* Specifically Mycostatin is indicated for the treatment of intestinal moniliasis and for protection against monilial superinfection during antimicrobial or corticosteroid therapy

Mycostatin Oral Tablets are compatible with all commonly employed anti microbial agents and may be given concomitantly with these agents Mycostatin Oral Tablets may be administered as a supplement in the local treatment of chronic or resistant oral vaginal or cutaneous moniliasis Mycostatin is worthy of trial in generalized (systemic) moniliasis

Dosage The usual prophylactic and therapeutic dose is 1 tablet (500 000 units) three times daily This dosage may be increased to 2 tablets (1 000 000 units) three times daily if intestinal fungi are not adequately suppressed When given concomitantly with an oral antibacterial agent Mycostatin should be continued at least as long as the antibacterial agent Treatment should generally be continued for at least 48 hours after clinical cure to prevent relapse

Note When monilial lesions of the skin and/or nasal vaginal or rectal mucosae are present in addition to intestinal infections these should be treated concomitantly with Mycostatin Ointment applied locally several times daily

Side Effects Mycostatin is virtually nontoxic and nonsensitizing and well tolera ted by all age groups including debilitated infants even on prolonged administration Large oral doses have occasionally produced diarrhoea and gastrointestinal distress

Presentation Mycostatin Oral Tablets sugar coated tablets of 500 000 units in bottles of 12

Expiration date 24 months

MYCOSTATIN® VIGINAL TABLETS — Vaginal Tablets

Nystatin Vaginal Tablets

Mycostatin is Nystatin an antifungal antibiotic with activity against a wide variety of yeasts and yeast like fungi Produced by a strain of *Strepto*

myces noursei Mycostatin is the first well tolerated antifungal antibiotic of dependable efficacy for the treatment of vaginal cutaneous oral and intestinal infections caused by *Candida* (Monilia) *albicans*

For the treatment of monilial infections of the vagina Mycostatin Vaginal Tablets are available as almond shaped compressed tablets supplying 100 000 units nystatin dispersed in a lactose base

Action In concentrations of 2 0 units/ml or more Mycostatin is fungistatic *in vitro* against a variety of yeast like fungi including the principal fungi pathogenic for man *In vivo* Mycostatin acts primarily against *Candida albicans* this action being fungicidal and fungistatic Mycostatin exhibits no appreciable activity against bacteria

Indications Mycostatin Vaginal Tablets are intended for the local treatment of vaginal mycotic infections caused by *Candida* (Monilia) *albicans* In both pregnant and non pregnant women Mycostatin offers an effective and painless control of such troublesome and unpleasant symptoms as itching inflammation and foul vaginal discharge commonly associated with monilial vaginitis Mycostatin Vaginal Tablets have proved useful in the control of *Candida albicans* vaginitis prior to delivery in gravid patients Reports in the literature indicate increasing evidence that the presence of *Candida albicans* in the birth canal at the time of delivery may be one of the major cause of thrush in the newborn

Local treatment with Mycostatin Vaginal Tablets may be supported by concomitant oral therapy with Mycostatin Oral Tablets particularly in chronic or recurrent cases when reinfection of the vagina from the intesti nal tract is suspected

Advantages Mycostatin Vaginal Tablets provide specific local therapy for vaginal moniliasis preserving the normal flora of the vaginal tract Restora tion of normal bacterial flora of the vagina is promoted by the lactose content of the tablets Symptomatic relief is rapid often occurring within 24 to 72 hours after initiation of treatment Cure is effected both clinically and mycologically in most cases of localized moniliasis

Administration and Dosage Mycostatin Vaginal Tablets are specifically de signed for ease of administration The almond shaped tablet should be inserted deep into the vagina once or twice daily The usual dosage of Mycostatin Vaginal Tablets for the treatment of monilial vaginitis in gravid and non-gravid patients is 1 or 2 tablets (100 000 or 200 000 units) intravaginally daily for two weeks or as required In most cases two weeks of therapy will be sufficient but in some cases more prolonged treatment may be necessary Adjunctive measures such as therapeutic douches are unnecessary and sometimes inadvisable Cleansing douches may be used by non pregnant women if desired for aesthetic purposes It is important that therapy be continued during menstruation In chronic or recurrent cases of monilial vaginitis when autoreinfection from the intestinal tract is suspected concomitant therapy with Mycostatin Oral Tablets 1 tablet (500 000 units) three times daily is advised

In gravid patients to prevent thrush in the newborn a dosage of 1 or 2 Mycostatin Vaginal Tablets daily for three to six weeks before term is suggested

Side Effects Mycostatin is virtually nontoxic and nonsensitizing and well tolerated by all age groups even on prolonged administration If irritation should occur discontinue medication

Presentation Each tablet containing 100 000 units strips of 12 tablets and boxes of 2 strips of 12 s

Expiration date 24 months Keep in a cool place

MYSTECLIN® 100 100 — Capsules

Tetracycline Hydrochloride and Nystatin

Mysteclin 100-100 is Tetracycline Hydrochloride and Nystatin The preparation is specifically designed to provide children in one capsule a broad spectrum antibiotic Tetracycline and an effective antifungal antibiotic Mycostatin® (Nystatin)

Tetracycline is a crystalline antibiotic resembling oxytetracycline and chlortetracycline in chemical configuration and antimicrobial activity However tetracycline offers the advantage of higher blood levels and fewer gastrointestinal side effects than its two analogues The antibiotic is well absorbed and diffuses readily into tissues and body fluids Nystatin is an antibiotic produced by a strain of *Streptomyces noursei* It is the first safe broadly effective antifungal antibiotic which has exhibited excellent fungistatic and fungicidal action against a wide variety of strains of *Candida* The drug is not appreciably absorbed from the gastrointestinal tract

Mysteclin 100-100 is available in capsules providing 100 mg tetracycline hydrochloride and 100 000 units nystatin

Rationale for Use Oral antibiotic therapy particularly with broad spectrum antibiotics may result in certain complications including gastrointestinal complaints diarrhoea lesions affecting the oral cavity (thrush) and anorectal disturbances which are attributable to an overgrowth of *Candida* (monilia) in the gastrointestinal tract In rare instances this may lead to systemic infections which are very difficult to control Fatal cases of moniliasis following intensive oral antibacterial therapy have been reported Mycostatin (Nystatin) has been employed successfully in the prevention and management of intestinal moniliasis particularly that occurring following the use of orally administered broad spectrum antibiotic The combined administration of Mycostatin (Nystatin) and Tetracycline as provided by Mysteclin 100 100 affords both antimicrobial therapy with a broad spectrum antibiotic as well as safe and effective prevention of overgrowth of *Candida* Mysteclin 100 100 is particularly useful in patients receiving prolonged or intensive tetracycline therapy and in individuals with debilitating diseases in whom an overgrowth of *Candida* may lead to fatal infection

It is also useful in infants (particularly prematures) as well as in any patient concurrently receiving cortisone or related steroid therapy and in subjects who have had a monilial complication on previous broad spectrum antibiotic therapy

Indications Mysteclin 100 - 100 is indicated for the many common infections including those of the respiratory gastrointestinal and genitourinary

systems which are amenable to tetracycline therapy Infections caused by gram positive and gram-nagative bacteria spirochaetes viruses of the lymphogranuloma psittacosis trachoma group rickettsiae and *Entamoeba histolytica* can be expected to respond

Representative infections in which Mysteclin 100 100 may be used are

Pheumococcal Infections
- lobar pneumonia

Streptococcal Infections
- cellulitis
- bronchopneumonia
- follicular tonsillitis
- meningitis
- otitis media
- pharyngitis
- scarlet fever
- septic sore throat
- tonsillitis
- tracheobronchitis
- urinary tract infections

Staphylococcal Infections
- abscesses
- acute bronchitis
- furunculosis
- impetigo
- laryngotracheitis
- ophthalmic infections
- osteomyelitis
- otitis media
- pharyngitis
- septicaemia
- sinusitis
- tracheobronchitis
- urinary tract infections

Neisseria Infections
- gonorrhoea
- meningitis

Proteus Infections (due to tetracycline sensitive strains)

Escherichia coli Infections
- abscesses
- peritonitis
- urinary tract infections

Shigella Infections
- bacillary dysentery

Haemophilus Infections

Pertussis

Rickettsial Infections
- epidemic typhus
- Rocky Mountain spotted fever

Virus like Infections
- lymphogranuloma
- psittacosis
- trachoma

Intestinal Amoebic Infections

Acute Brucellosis
- (in conjunction with streptomycin)

Mysteclin 100 100 is particularly valuable in the treatment of mixed infections and in conditions in which the causal agent has not been specifically identified for example pneumonia peritonitis chronic bronchiectasis sinusitis urinary tract infections and pancreatitis Mysteclin 100 100 is also recommended for mixed infections of the eye including conjunctivitis corneal infections periorbital infection and some forms of blepharitis and for such pyogenic dermatologic conditions as secondarily infected atopic dermatitis sycosis and eczematous otitis externa Mysteclin 100 100 is particularly useful in pre operative and post-operative prophylaxis

Administration and Dosage Infants and Children The dosage for infants and children is based on the tetracycline content of Mysteclin 100 100 Capsules so as to supply 20 mg/kg of body weight given in divided doses per day For example a child weighing 15 Kg should receive 1 Mysteclin 100 100 Capsule 3 times daily or a total of 300 mg tetracycline per day Dosage may be modified according to the type and severity of the infection being treated

For administration to infants the contents of a Mysteclin 100 100 Capsule may be added to soft foods such as jelly or custards Extemporaneous mixtures thus prepared should be used immediately

Treatment with Mysteclin 100 100 should be continued for at least 24 to 48 hours after symptoms have subsided and temperature has become normal Prolonged treatment may be necessary in some instances Sub acute bacterial endocarditis due to susceptible organisms may require one or more courses of therapy each lasting for a period of 6 to 8 weeks and acute staphylococcal infections several courses each of 10 to 14 days if necessary

When Mysteclin 100 100 is used for streptococcal respiratory infections in penicillin sensitive patients administration of the drug should be con tinued for 10 days It has been found that rheumatic fever can be prevented in most instances if adequate blood concentrations are maintained for 10 days

Side Effects Since not all gastrointestinal side effects are due to moniliasis nausea vomiting and diarrhoea may occur in some patients However tetracycline is generally well tolerated undesirable gastrointestinal side effects occurring significantly less frequently than with its two analogues oxytetracycline and chlortetracycline Apart from those side effects arising from monilial infections which are largely eliminated the incidence and severity of side effects following combined use of tetracycline and nystatin is no greater than that occurring following the use of tetracycline alone

Precaution Mysteclin 100 100 therapy should be given under the constant supervision of a physician

Presentation Bottles of 12 capsules

Expiration date 18 months

MYSTECLIN® **Capsules**

Tetracycline Hydrochloride and Amphotericin B (Fungizone®)

Mysteclin Capsules contain 250 mg crystalline tetracycline hydrochloride and 50 mg amphotericin B (Fungizone) Although the chemical and physical properties as well as the antibacterial spectrum of tetracycline hydrochloride resemble those of oxytetracycline and chlortetracycline tetracycline hydrochloride offers the advantage of greater stability in plasma and on oral administration few gastrointestinal side effects In addition tetracycline hydrochloride rapidly achieves effective blood and tissue concentrations

Action Tetracycline hydrochloride provides proven therapeutic effectiveness against infections caused by a broad spectrum of micro organisms includ ing both gram positive and gram negative bacteria spirochaetes certain rickettsiae viruses of the lymphogranuloma psittacosis trachoma group and *Endamoeba histolytica* Following oral administration tetracycline hydrochloride is readily absorbed from the gastrointestinal tract with prompt establishment of fully effective blood concentrations The antibiotic

is rapidly diffused into various body fluids including the cerebrospinal peritoneal and pleural fluids and the saliva It appears to be mainly excreted in the urine although some portions of the ingested drug are excreted unchanged in the faeces

Mysteclin also contains prophylactic amounts of amphotericin B (Fungizone) for specific protection against monilial overgrowth in the gastrointestinal tract Monilial overgrowth may occur in some patients taking broad spectrum antibiotics – particularly elderly or debilitated patients patients on high or prolonged antibiotic dosage diabetics infants especially prematures patients on corticoid therapy patients who have developed moniliasis on previous broad spectrum therapy and women particularly during pregnancy These patients especially are potential candidates for therapy with Mysteclin Capsules whenever tetracycline antibiotics are indicated

Indications Mysteclin Capsules are indicated for the many common infections including those of the respiratory gastrointestinal and genitourinary systems which are amenable to tetracycline therapy

Representative infections in which Mysteclin Capsules may be used are

Pneumococcal Infections
- lobar pneumonia

Streptococcal Infections
- cellulitis
- bronchopneumonia
- follicular tonsillitis
- meningitis
- otitis media
- pharyngitis
- scarlet fever
- septic sore throat
- tonsillitis
- tracheobronchitis
- urinary tract infections

Staphylococcal Infections
- abscesses
- acute bronchitis
- furunculosis
- impetigo
- laryngotracheitis
- ophthalmic infections
- osteomyelitis
- otitis media
- pharyngitis
- septicaemia
- sinusitis
- tracheobronchitis
- urinary tract infections

Neisseria Infections
- gonorrhoea
- meningitis

Proteus Infections (due to tetracycline sensitive strains)

Escherichia coli Infections
- abscesses
- peritonitis
- urinary tract infections

Shigella Infections
- bacillary dysentery

Haemophilus Infections

Pertussis

Rickettsial Infections
- epidemic typhus
- Rocky Mountain spotted fever

Virus like Infections
- lymphogranuloma
- psittacosis
- trachoma

Intestinal Amoebic Infections

Acute Brucellosis
- (in conjunction with streptomycin)

Mysteclin Capsules are particularly valuable in the treatment of mixed

infections due to susceptible organisms and in conditions in which the causal agent has not been specifically identified for example pneumonia peritonitis chronic bronchiectasis sinusitis urinary tract infections post partum endometritis puerperal mastitis and pancreatitis The capsules are also recommended for mixed infections of the eye including conjunctivitis corneal infection periorbital infection uveitis and some forms of blepharitis and for such pyogenic dermatologic conditions as secondarily infected atopic dermatitis sycosis and eczematous otitis externa The capsules are also useful in pre operative and post operative prophylaxis

Dosage Dosage should be based on the tetracycline content The suggested *minimum* adult dosage is 250 mg four time daily Higher dosages such as 500 mg four times daily may be required for severe infections or for those infections which do not respond to the smaller dose In general the paediatric dosage should supply 20 to 40 mg tetracycline per kg of body weight each day in divided doses depending on the type and severity of the infection

Treatment of most common infections should generally continue for 24 to 48 hours after symptoms and fever subside However if the capsules are used in the treatment of streptococcal infections therapy should be continued for a full 10 days to guard against the risk of rheumatic fever or glomerulonephritis Even more prolonged therapy is necessary for sub acute bacterial endocarditis and may be required in certain staphylococcal infections

Side Effects Tetracycline hydrochloride is generally well tolerated Undesirable side effects such as nausea vomiting and diarrhoea are significantly less frequent with tetracycline hydrochloride than with the two analogues oxy tetracycline and chlortetracycline

Precautions As with any antibiotic preparation prolonged use may result in overgrowth of non-susceptible organisms Constant observation of the patient is essential Should superinfection occur the drug should be discontinued and/or appropriate therapy instituted

Tetracycline may form a stable calcium complex in any bone forming tissue with no serious harmful effects reported thus far in humans However use of tetracycline during tooth development (i e last trimester of pregnancy neonatal period and early childhood) may cause discolouration of the teeth (i e yellow-grey-brownish) This effect occurs mostly during long term use of the drug but it has also been observed in usual short treatment courses

Warning If renal impairment exists even usual oral or parenteral doses may lead to excessive systemic accumulation of the drug and possible liver toxicity Under such conditions lower than usual doses are indicated and if therapy is prolonged tetracycline serum level determinations may be advisable

Presentation Vials of 4 capsules and boxes of 25 vials of 4 s

Expiration date 24 months

MYSTECLIN-V® IMPROVED PEDIATRIC DROPS Liquid

Tetracycline Buffered with Potassium Metaphosphate and Amphotericin B (Fungizone®)

Mysteclin-V Improved Pediatric Drops provide in a form particularly well suited for paediatric use Each ml of Mysteclin V Improved Pediatric Drops contains tetracycline equivalent to 100 mg tetracycline hydrochloride buf fered with potassium metaphosphate and 20 mg amphotericin B in a fruit flavoured aqueous preparation The preparation also contains 0 2% sodium benzoate and 0 15% sodium metabisulphite as preservatives

Mysteclin V Improved Pediatric Drops are supplied with a dropper wh ch dispenses 5 mg tetracycline and 1 mg amphotericin B per drop (25 mg tetracycline and 5 mg amphotericin B in 5 drops)

Action Mysteclin V Improved has been designed to provide simultaneous antimicrob al therapy and antimonilial prophylaxis

Mysteclin V Improved contains the broad spectrum antibiotic tetracycline well known for its pronounced antimicrobial effect against a wide range of pathogenic organisms Mysteclin V Improved produces exceptionally high initial tetracycline blood levels as well as excellent diffusion to tissues and body fluids

Furthermore Mysteclin V Improved also contains prophylactic amounts of the antifungal antibiotic Fungizone (Amphotericin B) which is substantially more active *in vitro* against *Candida* strains than nystatin It has been widely used by the intravenous route in the successful treatment of many deep seated mycotic infections

Given orally Fungizone is extremely well tolerated and is virtually non toxic in prophylactic doses Since it is poorly absorbed from the gastrointestinal tract after oral administration Fungizone exerts a high degree of activity against *Candida* species in the intestinal tract and prevents the overgrowth of these organisms commonly associated with broad spectrum antibiotic therapy (Fungizone has no antibacterial activity) By suppressing over growth of *Candida* in the gastrointestinal tract thereby minimizing a possi ble reservoir of this organism Mysteclin V Improved provides added protection for the patient against potentially troublesome or even serious monilial superinfections e g intestinal anogenital mucocutaneous moniliasis

Indications Mysteclin V Improved is indicated for the many common infec tions including those of the respiratory gastrointestinal and genitourinary systems which are amenable to tetracycline therapy Infections caused by gram-positive and gram negative bacteria spirochaetes organisms of the lymphogranuloma psittacosis-trachoma group rickettsiae and *Entamoeba histolytica* can be expected to respond Because of its wide range of antimicrobial activity Mysteclin V Improved is particularly useful in the treatment of mixed infections due to susceptible organisms Monilial overgrowth may occur in patients taking broad spectrum antibiotics Although it is impossible to predict exactly which paediatric patient will develop

monilial complications and which will not certain types of patients are known to be particularly susceptible to moniliasis Among these are infants particularly premature debilitated patients such as in kwashiorkor patients on high or prolonged antibiotic dosage diabetics patients on corticoid therapy and patients who have developed moniliasis on previous broad spectrum therapy Because the danger of monilial complications is greatest in these patients they are candidates for therapy with Mysteclin V Improved

Dosage Mysteclin V Improved dosage should be based on its tetracycline content In general the paediatric dosage should supply 20 to 40 mg tetracycline per kg of body weight each day in divided doses depending on the type and severity of the infection The following paediatric dosages are representative

Below 5 kg	25 mg tetracycline (5 drops) four times daily
5 to 10 kg	50 mg tetracycline (10 drops) four times daily
10 to 15 kg	75 mg tetracycline (15 drops) four times daily
15 to 20 kg	100 mg tetracycline (20 drops) four times daily

Treatment of most common infections should continue for 24 to 48 hours after symptoms and fever subside However if Mysteclin V Imp oved is used in the treatment of streptococcal infections therapy should be con tinued for a full 10 days to guard against the risk of rheumatic fever higher dosage and even more prolonged therapy would be necessary for sub-acute bacterial endocarditis and might be required for certain staphylo coccal infections

Precautions With the use of any broad spectrum antibiotic the patient should be carefully watched for signs of secondary infection caused by non susceptible organisms If such infections appear Mysteclin-V Improved should be discontinued and/or other appropriate measures taken

Side Effects Since not all gastrointestinal side effects are due to moniliasis nausea vomiting and diarrhoea may occur in some patients However tetracycline is generally well tolerated undesirable gastrointestinal side effects occurring significantly less frequently than with the two analogues oxytetracycline and chlortetracycline

Warning If renal impairment exists even usual oral or parenteral doses may lead to excessive systemic accumulation of the drug and possible liver toxicity Under such conditions lower than usual doses are indicated and if therapy is prolonged tetracycline serum level determinations may be advis-able

Presentation Bottles of 5 ml and 10 ml with dropper

Expiration date 18 months

and *Entamoeba histolytica* Following oral administration tetracycline

MYSTECLIN-V® IMPROVED SYRUP — Syrup

Tetracycline Buffered with Potassium Metaphosphate and Amphotericin B (Fungizone®)

Mysteclin V Improved Syrup provides Tetracycline and Amphotericin B (Fungizone) in a form particularly well suited for children Each 5 ml of Mysteclin-V Improved Syrup contains tetracycline equivalent to 125 mg tetracycline hydrochloride buffered with potassium metaphosphate and 25 mg amphotericin B in a pleasantly flavoured syrup

A 5 ml spoon measure is supplied with each Mysteclin V Improved Syrup

Action Mysteclin V Improved Syrup has been designed to provide simultaneous antimicrobial therapy and antimonilial prophylaxis Mysteclin V Improved Syrup contains the broad spectrum antibiotic tetracycline well known for its pronounced antimicrobial effect against a wide range of pathogenic organisms Mysteclin V Improved Syrup produces high initial tetracycline blood levels as well as excellent diffusion to tissues and body fluids

Furthermore Mysteclin V Improved Syrup also contains prophylactic amounts of the antifungal antibiotic Fungizone (Amphotericin B) which is substantially more active *in vitro* against *Candida* strains than nystatin It has been widely used by the intravenous route in the successful treatment of many deep seated mycotic infections

Given orally Fungizone is extremely well tolerated and is virtually non-toxic in prophylactic doses Since it is poorly absorbed from the gastrointestinal tract after oral administration Fungizone exerts a high degree of activity against *Candida* species in the intestinal tract and prevents the overgrowth of these organisms commonly associated with broad spectrum antibiotic therapy (Fungizone has no antibacterial activity) By suppressing overgrowth of *Candida* in the gastrointestinal tract thereby minimizing a possible reservoir of this organism Mysteclin-V Improved Syrup provides added protection for the patient against potentially troublesome or even serious monilial superinfections e g intestinal anogenital mucocutaneous moniliasis

Indications Mysteclin-V Improved Syrup is indicated for the many common infections including those of the respiratory gastrointestinal and genitourinary systems which are amenable to tetracycline therapy Infections caused by gram positive and gram negative bacteria spirochaetes organisms of the lymphogranuloma-psittacosis trachoma group rickettsiae and *Entamoeba histolytica* can be expected to respond Because of its wide range of antimicrobial activity Mysteclin-V Improved Syrup is particularly useful in the treatment of mixed infections due to susceptible organisms

Monilial overgrowth may occur in patients taking broad spectrum antibiotics Although it is impossible to predict exactly which patient will develop monilial complications and which will not certain types of patients are known to be particularly susceptible to moniliasis Among these are infants particularly premature debilitated patients patients on high or prolonged antibiotic dosage diabetics patients on corticoid therapy and patients who have developed moniliasis on previous broad spectrum therapy Because the danger of monilial complications is greatest in these patients

they are candidates for therapy with Mysteclin V Improved Syrup

Dosage The dosage of Mysteclin V Improved Syrup should be based on its tetracycline content In general the paediatric dosage should supply 20 40 mg tetracycline per kg of body weight per day in divided doses depending upon the severity of infection The following dosage schedule will usually be found to be adequate

Body weight		*Dose*
9 kg (20 lbs approx)	=	½ teaspoonful q i d
18 kg (40 lbs approx)	=	1 teaspoonful q i d
27 kg (60 lbs approx)	=	1½ teaspoonfuls q i d
36 kg (80 lbs approx)	=	2 teaspoonfuls q i d

It is recommended that treatment with Mysteclin V Improved Syrup should continue for one or two days after symptoms and fever subside However for streptococcal infections therapy with Mysteclin V Improved Syrup should be continued for 10 more days after the fever has subsided to guard against the risk of rheumatic fever higher dosage and even more prolonged therapy would be necessary for subacute bacterial endocarditis and might be required for certain staphylococcal infections

Precautions With the use of any broad spectrum antibiotic the patient should be carefully watched for signs of secondary infection caused by non susceptible organisms If such infections appear Mysteclin-V Improved Syrup should be discontinued and/or other appropriate measures taken

Side Effects Since not all gastrointestinal side effects are due to moniliasis nausea vomiting and diarrhoea may occur in some patients However tetracycline is generally well tolerated undesirable gastrointestinal side effects occurring significantly less frequently than with the other analogues of tetracycline

Warning If renal impairment exists even usual oral or parenteral doses may lead to excessive systemic accumulation of the drug and possible liver toxicity Under such conditions lower than usual doses are indicated and if therapy is prolonged tetracycline serum level determinations may be advis able

Presentation Bottles of 60 ml with a 5 ml spoon measure

Note Keep tightly closed in a cool place protected from light

Expiration date 18 months

NAVITOL® MALT COMPOUND — Syrup

Syrup of Vitamins with Iron

Navitol Malt Compound is an agreeable vitamin iron dietary supplement especially for children One tablespoonful (½ fluid ounce or 20 grammes) the suggested daily dose of Navitol Malt Compound supplies

Vitamin A	5 000 I U
Vitamin D	1 000 I U
Vitamin B_1 (Thiamine Hydrochloride)	1 mg
Vitamin B_2 (Riboflavine)	1 5 mg
Niacinamide	10 mg
Iron as ferrous sulphate	10 mg

and is composed of 63 0 per cent carbohydrate 1 4 per cent fat 5 3 per cent protein 1 5 per cent ash and 61 calories per ½ fluid ounce (1 table spoonful)

Advantages Navitol Malt Compound is a thick dark brown prune like flavoured syrup that is ideal for children Their co operation is encouraged by this agreeable preparation One tablespoonful of Navitol Malt Compound supplies the full recommended dietary allowances of the three important B Complex vitamins and Iron for children seven to nine years of age (the median age group) It also supplies a dosage of vitamins A and D which is the recognized optimum in paediatric practice

Dosage One tablespoonful daily or more as directed by the physician

Presentation Bottles of 225 g and 450 g

Note Keep in a cool place in order to avoid vitamin B_1 loss

Expiration date 18 months

NYDRAZID® — Tablets Sterile Solution

Isoniazid

Nydrazid is Isoniazid a potent antituberculous drug It is available as tablets providing 50 mg 100 mg and 300 mg isoniazid For intramuscular use Nydrazid is available in vials of 10 ml each ml providing 100 mg isoniazid Intramuscular administration of Nydrazid is intended for use whenever the oral route of administration is not possible Nydrazid Injection may also be employed topically for tuberculous empyema or effusion The intramuscular preparation may crystallize at low temperatures and should be warmed to room temperature to ensure solution before use

Advantages Following administration Nydrazid is distributed throughout the body tissues and fluids The drug penetrates readily into necrotic tuberculous tissue and is effective against intracellular organisms

Indications Nydrazid is recommended in the treatment of tuberculosis preferably in conjunction with other antituberculous drugs Nydrazid like any other antituberculous drug must be considered an adjuvant in the careful long range management of tuberculosis As is true of other antituberculous drus the chief short coming of isoniazid lies in the emergence of resistant organisms suggesting combined use of isoniazid with other antitubercu lous agents Clinical experience has shown that due to synergism concomitant administration of isoniazid with streptomycin and/or Etinol 400 mg Tablets (Ethambutol) may provide an increased antituberculous effect

and tends to prevent or delay development of resistant organisms Nydrazid has proved useful in the treatment of Hansen s disease (Leprosy) favourable results having been observed particularly in patients with the lepromatous type of the disease

Nydrazid is also recommended for oral prophylactic use in all infants and children under 3 years of age who exhibit positive reactions to either the Mantoux or the tuberculin patch test and to all children who have recently converted from a nagative to positive tuberculin reaction

Precautions In patients with epilepsy isoniazid should be administered cautiously and only when the epileptic condition has been controlled with appropriate medication Isoniazid should be given with caution and in the lowest effective doses where renal damage is suspected or known to exist The drug should not be used in the treatment of renal tuberculosis unless adequate facilities for the estimation of isoniazid blood levels are available Detection of isoniazid levels is readily accomplished by chemical analysis

Side Effects Undesirable side effects are generally minimal with therapeutic doses of isoniazid Untoward effects are limited to central nervous system stimulation including hyper reflexia paraesthesias vertigo drowsiness excitement euphoria delay in micturition muscular twitching dryness of the mouth and peripheral neuritis These reactions are more likely to occur in elderly patients than in young children and adolescents Concomitant administration of pyridoxine with isoniazid is used to prevent or control peripheral neuritis If signs of marked central nervous system stimulation are encountered isoniazid therapy should be interrupted

Administration and Dosage CLINICAL APPLICATION – The recommended dosage for isoniazid in the treatment of tuberculosis or Hansen s disease is 3 to 5 mg/kg of body weight per day either in a single dose or in divided doses In serious cases of tuberculosis such as miliary or meningeal tuberculosis the recommended daily dosage for isoniazid is 7 mg/kg for seven days and thereafter 3 mg/kg Oral dosage should be given with meals

Usually for an adult patient one 100 mg tablet is given three times a day however for convenience of once a day dosage one 300 mg tablet can be recommended every day

For oral prophylaxis or for oral or parenteral therapy in infants and children who are rapid inactivators of isoniazid the recommended daily dosage is 10 to 20 mg/kg of body weight (maximum dosage 500 mg daily) divided into two equal doses i e 5 to 10 mg/kg b i d

Presentation Tablets 50 mg bottles of 1000 100 mg bottles of 100 and 1000 and tins of 2500 300 mg bottles of 250

Injection 100 mg per ml 10 ml vials

Expiration date 18 months for Nydrazid Injection

NYZET® Tablets

NYZET® FORTE Tablets

Isoniazid (Nydrazid®) – Thiacetazone

Nyzet and Nyzet Forte are Isoniazid and Thiacetazone combinations for antituberculous therapy Nydrazid isoniazid and thiacetazone are individually potent antituberculous drugs As is true of other antituberculous agents the chief shortcoming of isoniazid and thiacetazone when given alone lies in the emergence of resistant organisms Clinical experience has shown that combination of isoniazid with thiacetazone can provide an increased antituberculous effect and tends to prevent or delay development of resistant organisms This combination has proved to be an ideal choice as the second line of treatment It can be used even as the first line of treatment in patients unable to tolerate the streptomycin drugs Nyzet and Nyzet Forte can be given in combination with streptomycin therapy also Each Nyzet Tablet provides 75 mg of isoniazid and 37 5 mg of thiacetazone while each Nyzet Forte Tablet provides 300 mg of isoniazid and 150 mg of thiacetazone

Administration and Dosage Nyzet and Nyzet Forte Tablets are administered orally The most effective dosage is 300 mg of isoniazid combined with 150 mg of thiacetazone (The dosage is to be based on the isoniazid content the recommended dosage for isoniazid being 3 to 5 mg/kg body weight) Thus the usual adult dose will be one Nyzet Tablet four times a day as divided doses or one Nyzet Forte Tablet a day as a single dose Oral dosages should be given preferably with meals The duration of the therapy and concomitant use of other antituberculous agents will have to be decided by the physician and will depend on the clinical bacteriological and radiological follow up

Side Effects Undesirable side effects are generally minimal with therapeutic doses of Nyzet and Nyzet Forte Untoward effects are limited to central nervous system stimulation including hyper reflexia paraesthesias vertigo drowsiness excitement euphoria delay in micturition muscular twitching dryness of mouth and peripheral neuritis Liver damage anaemia agranulocytosis and proteinurea are also occasionally described It is advisable for patients on Nyzet therapy to have periodical examination of urine and blood picture Skin hypersensitivity reactions are also reported Early administration of antihistamines can be of help If the reaction is severe the drug should be discontinued

Precautions The drug should be used with caution in patients with epilepsy renal damage or liver damage

Presentation Nyzet – Nested packing of 1000 tablets (10 bottles of 100 s) Nyzet Forte – Bottles of 30 tablets and nested packings of 1000 tablets (10 bottles of 100 s)

OXYSTECLIN®

Parenteral Solution

Oxytetracycline Intramuscular

Oxysteclin (Oxytetracycline Intramuscular) is a ready solution providing 50 mg and 125 mg Oxytetracycline per ml along with 2% lidocaine as anaesthetic agent in multi dose vials and single-dose ampoules

Action Oxysteclin (Oxytetracycline Intramuscular) is a potent antimicrobial agent It rapidly attains fully effective blood and tissue levels It is excreted through bile and urine in biologically active form In general tetracyclines are primarily used for the treatment of gram negative bacillary infections rickettsial diseases and gram positive infections amenable to oxytetracycline It is also effective against the lymphogranuloma-psittacosis trachoma group

Indications Oxysteclin (Oxytetracycline Intramuscular) exhibits antimicrobial activity against a wide variety of gram-negative and gram-positive bacteria rickettsiae spirochaetes *Entamoeba histolytica* and organisms of the lymphogranuloma-psittacosis trachoma group

This preparation is particulary valuable in the treatment of mixed infections and in conditions in which the causal agent has not been specifically identified The preparation is also recommended for the mixed infections of eye and for such pyogenic dermatologic conditions as secondarily infected atopic dermatitis sycosis and eczematous otitis externa

Intramuscular oxytetracycline therapy is intended for those patients who are unable or unwilling to take oral therapy

Note A number of strains of *Staphylococci* and *Streptococci* have shown resistance to tetracyclines A few strains of *Pneumococci E coli* and *Shigellae* also have been reported as resistant Indicated laboratory studies including sensitivity tests should be performed

Contraindications This drug is contraindicated in individuals with a history of hypersensitivity to oxytetracycline or lidocaine

Warning If renal impairment exists even usual oral or parenteral doses may lead to excessive systemic accumulation of the drug and possible liver toxicity Under such conditions lower than usual doses are indicated and if therapy is prolonged oxytetracycline serum level determination may be advisable

Certain hypersensitive individuals may develop a photodynamic reaction precipitated by a direct exposure to natural or artificial sunlight during the use of this drug This reaction is usually of the photoallergic type which may also be produced by other tetracycline derivatives Individuals with a history of photosensitivity reactions should be instructed to avoid direct exposure to natural or artificial sunlight while under treatment with this or other tetracycline drugs and treatment should be discontinued at first evidence of skin discomfort

Note Photosensitization reactions have occurred most frequently with dimethylchlortetracycline and very rarely with oxytetracycline and tetra cycline

Precautions Since sensitivity reactions are more likely to occur in persons with a history of allergy asthma hay fever or urticaria the preparation should be used with caution in such individuals Cross sensitization among the various tetracyclines is extremely common

As with any preparation for intramuscular injection care should be taken to ensure intramuscular delivery (see *Administration and Dosage*)

During long term therapy periodic assessment of organ system function including renal hepatic and haematopoietic systems should be made

As with any antibiotic preparation prolonged use may result in overgrowth of non susceptible organisms Constant observation of the patient is essential Should superinfection occur the preparation should be discontinued and/or appropriate therapy instituted

Note Superinfection of the bowel by staphylococci may be life threatening

Oxytetracycline may form a stable calcium complex in any bone-forming tissue However use of oxytetracycline during tooth development (i e latter half of gestation neonatal period and early childhood) may cause discolouration of the teeth (i e yellow grey brownish) This effect occurs mostly during long term use of the drug but it has also been observed in usual short treatment courses

Adverse Reactions Tetracycline in general may produce gastrointestinal irritation (anorexia epigastric distress nausea vomiting) as well as bulky loose stools and diarrhoea Glossitis stomatitis enterocolitis proctitis and pruritus ani may occur in some patients Black hairy tongue sore throat dysphagia and hoarseness have been reported The gastrointestinal side effects are less frequent after parenteral use than after oral administration

Maculopapular and erythematous skin rashes may occur A rare case of exfoliative dermatitis has been reported Photosensitivity manifested by an exaggerated sunburn reaction has been observed in some individuals (see *Warning*) Onycholysis and discolouration of the nails have been reported rarely

Rise in BUN (Blood Urea Nitrogen) has been reported and is apparently dose related Urinary loss of nitrogen has been observed in some patients receiving tetracyclines and may result in negative nitrogen balance Increased excretion of sodium has also been reported The development of peptic ulcers and bleeding has been observed in uremic patients receiving tetracyclines

Hypersensitivity reactions may include urticaria serum sickness like reactions (fever rash arthralgia) angioneurotic oedema and anaphylactoid shock If allergic reactions occur or if an individual idiosyncrasy appears oxytetracycline therapy should be discontinued

The use of oxytetracycline during the mineralization phase of tooth development (latter half of gestation neonatal period and early childhood) may cause discolouration of the teeth (yellow grey brownish) which may sometimes be accompanied by enamel hypoplasia (see *Precautions*)

Anaemia thrombocytopenic purpura neutropenia and eosinophilia have been reported Tetracyclines may delay blood coagulation

Hepatic cholestasis has been reported rarely and is usually associated with high dosage levels

Administration and Dosage Adults Intramuscular administration of 200 to 300 mg per day given in divided doses of 100 mg every 8 to 12 hours or as a single daily dose of 250 mg is generally adequate for the treatment of susceptible infections of mild or moderate severity In more severe infections or in those patients not responding to the above dosage schedule 250 mg every 12 hours may be necessary

Infants and Children Dosage for infants and children should be proportionately less than the adult dose depending on the age weight and severity of the condition being treated

Note Therapy should be continued 1 or 2 days after signs and symptoms of the disease being treated have subsided However if an oxytetracycline preparation is used to treat haemolytic streptococcal infections therapy should be continued for at least 10 days to guard against the risk of rheumatic fever or glomerulonephritis Even more prolonged therapy is necessary for subacute bacterial endocarditis and may be required in certain staphylococcal infections

When using Oxysteclin (Oxytetracycline Intramuscular) in the treatment of brucellosis the course of therapy should be three weeks and supplemented with intramuscular injections of streptomycin in a dosage of 1 g twice daily the first week and 1 g daily the second and third weeks in adults In children the dosage should be adjusted according to the age and weight of the patient

Presentation Oxysteclin is available in the following packings
Ampoules of 2 ml (50 mg/ml and 125 mg/ml)
Vials of 10 ml (50 mg/ml)

Also available Oxytetracycline Injection Vials of 20 ml (50 mg/ml)

Note Store in a cool dry place protected from light

Expiration date 24 months

PENICILLIN G PROCAINE CRYSTALLINE IN OIL (with Aluminum Monostearate)

Parenteral Suspension

Each ml Penicillin G Procaine in Oil provides 300 000 units crystalline micronized procaine penicillin G suspended in sesame oil with 2 % aluminum monostearate It is supplied in vials of 10 ml

Action Because of its low water solubility penicillin G procaine is slowly absorbed by the tissues With the addition of aluminum monostearate absorption takes place even more slowly and more uniformly Penicillin G procaine in oil with 2 % aluminum monostearate produces persistent blood levels for at least 24 hours after administration of 300 000 u The prolonged blood concentrations are shortened with ambulatory patients

Prolonged penicillin blood levels do not necessarily mean that the drug is present in therapeutically effective amounts and the dosage suggested in this monograph may therefore need to be adjusted accordingly

Indications The principal field of usefulness of penicillin G procaine in oil with aluminum monostearate is the treatment for conditions caused by organisms with a low penicillin resistance – 0 1 u or less penicillin/ml serum – particularly those organisms requiring prolonged exposure to the drug

Contraindications This preparation is contraindicated in patients with a history of sensitivity to either procaine or penicillin

Precautions As with any antibiotic preparation prolonged use may result in overgrowth of non susceptible organisms including fungi Constant observation of the patient is essential Should superinfection occur the drug should be discontinued and/or appropriate therapy instituted

Where procaine sensitivity is suspected perform a preliminary intradermal skin test If the test is positive do not administer procaine penicillin

Preliminary intradermal skin test to detect penicillin sensitivity should be performed routinely to avoid severe anaphylactic reaction Intradermal test may also give rise to anaphylactic reaction in sensitive individuals hence measures to combat such reaction should be available

Adverse Reactions Toxic reactions due to penicillin have been largely limited to sensitivity phenomena Such reactions may include urticaria serum sickness like reactions (fever rash arthralgia) other skin rashes and rarely anaphylactoid shock They are more likely to occur in individuals with a history of allergy asthma hay fever or urticaria and in those who have previously demonstrated hypersensitivity to penicillin Urticarial serum sickness like and other skin rash reactions may be controlled by antihistamines and if necessary corticosteroids Whenever such reactions occur penicillin should be discontinued unless in the opinion of the physician the condition being treated is life threatening and amenable only to penicillin therapy Serious anaphylactoid reactions are not controlled by antihistamines and require such measures as the immediate use of epinephrine oxygen intravenous corticosteroids and intravenous fluids

Administration Procaine Penicillin G Suspension is administered by deep intramuscular injection changing the site for each injection the preferred site is the upper outer quadrant of the buttock High dosages should be distributed over several injection sites

1 Use a 20 gauge needle
2 Shake the vial vigorously to form a uniform suspension
3 Inject air into the vial for easier withdrawal
4 After withdrawing dose into the syringe make sure needle is empty by pulling back the plunger until a small air bubble appears
5 Insert needle and aspirate to be sure needle is not in a vein
6 Inject dose slowly Do not massage the injection site
7 Wash needle and syringe in warm water and soap immediately

Dosage The recommended daily dosage of Procaine Penicillin G Suspension for most penicillin susceptible infections (except venereal disease) is 300 000 u and at least 150 000 u for small children In severe infections

300 000 u every 12 hours is suggested Streptococcal infections should be treated for 10 days in order to guard against the risk of rheumatic fever or glomerulonephritis

In syphilis the following dosages are suggested

Primary or Secondary Syphilis and Latent Syphilis with Negative Spinal Fluid A total of 4 800 000 u with 2 400 000 u administered at the first session (1 200 000 u in each buttock) followed by two injections of 1 200 000 u each at two to three day intervals

Latent Syphilis with no Spinal Fluid Examination Dosage is the same as for asymptomatic neurosyphilis (see following paragraph)

Late Syphilis (including symptomatic and asymptomatic neurosyphilis cardiovascular osseous cutaneous and visceral) A total of 6 000 000 to 9 000 000 u administered 1 200 000 u at three day intervals Any benefit from more than 10 000 000 u has not been demonstrated

Early Congenital Syphilis (children under 2 years of age) Dosage is adjusted to age and body weight A total of 100 000 u per kg should be given in divided doses at two to three day intervals

Late Congenital Syphilis Treatment is the same as for corresponding stages of acquired syphilis However in children under 12 dosage should be adjusted to age and body weight Interstitial keratitis usually does *not* respond to penicillin The addition of corticosteroids applied locally to the eyes is recommended

Syphilis in Pregnancy Treatment should correspond to the stage of the disease

Complications such as cardiovascular syphilis in circulatory failure will require specific measure in addition to penicillin As a minimum dose 6 000 000 to 10 000 000 u is recommended to maintain an adequate blood level for about 8 days This dose may be supplemented by additional penicillin or other therapeutic measures as indicated

All cases of penicillin treated syphilis should receive clinical and serological examinations every six months for at least two or three years

In gonorrhoea the following dosage schedules are suggested

Uncomplicated Gonorrhoea in Males 1 200 000 u in one intramuscular injection If discharge persists for three days or more after initial treatment and smear or culture remains positive re treat with a single dose of 2 400 000 u or the amount may be divided into 2 injections to be given in two buttocks consecutively

Uncomplicated Gonorrhoea in Females 2 400 000 u intramuscularly

Gonorrhoea with Complications (eye involvement prostatitis arthritis etc) Use aqueous penicillin G 600 000 to 1 200 000 u per day at 2 to 4 hour intervals or equivalent doses of repository penicillin until signs and symptoms have subsided

In the treatment of gonorrhoea patients with a suspected lesion of syphilis should have darkfield examinations before receiving penicillin and monthly serologic tests for a minimum of three months

Presentation Vials of 10 ml 3 000 000 units (300 000 units per ml)

Note No refrigeration required The material may settle somewhat on standing A brisk shaking of vial readily suspends the contents uniformly

Expiration date 36 months at room temperature

PENICILLIN G SODIUM CRYSTALLINE BUFFERED — Sterile Powder

Penicillin G Sodium is crystalline sodium penicillin G as sterile powder buffered with 4 5% (w/w) Sodiun Citrate (calculated as anhydrous) It is suitable for intramuscular and intravenous use as well as for intrapleural or other local instillation

Advantages

- suitable for intramuscular and intravenous use
- suitable for intrapleural intra articular or other local instillation
- provides high se um concentration of penicillin
- produces rapid effect

Indications Buffered penicillin G is used when apid effect or high serum concentrations of penicillin are sought Penicillin is effective only when the causative organ sm is penicillin susceptible and dosage is sufficient to produce bacteriostatic or bactericidal concentrations at the site of infec tion for a period sufficient to allow body defences to eradicate the infec tions

Contraindications This drug is contraindicated in individuals with a history of previous hypersensitivity to it

Precautions As with any antibiotic preparation prolonged use may result in overgrowth of non susceptible organisms including fungi Constant obser vation of the patient is essential Should superinfection occur the pre paration should be discontinued and/or appropriate therapy instituted

Preliminary intradermal skin test to detect penicillin sensitivity should be performed routinely to avoid severe anaphylactic reaction Intradermal test may also give rise to anaphylactic reaction in sensitive individuals hence measures to combat such reaction should be available

In the treatment of gonorrhoea where concomitant syphilis is suspected make darkf eld examination before treatment and serologic tests monthly for three months

Adverse Reactions Adverse reactions due to penicillin have been largely limited to sensitivity phenomena Such reactions may include urticaria serum sickness like reactions (fever rash arthralgia) other skin rashes and rarely anaphylactoid shock

They are more likely to occur in ir dividuals with a history of allergy asthma hay fever or urticaria and in those who have previously demonstrated hypersensitivity to penicillin Urticarial serum sickness-like and other skin rash reactions may be controlled by antihistamines and if necessary

corticosteroids Whenever such reactions occur penicillin should be discontinued unless in the opinion of the physician the condition being treated is life threatening and amenable only to penicillin therapy Serious anaphylactoid reactions are not controlled by antihistamines and require such measures as the immediate use of epinephrine oxygen intravenous corticosteroids and intravenous fluids

Administration Buffered penicillin G may be given intramuscularly or by continuous intravenous drip It is also suitable for intrapleural intra articular or other local instillations

1 *Intramuscular Injection* Keep total volume of individual injection small If desired large doses may be divided and injected into more than one site to reduce the severity of discomfort

2 *Continuous Intravenous Drip* Determine the volume of fluid and rate of its administration required by the patient in a 24 hour period in the usual manner of fluid therapy and add the appropriate daily dosage of penicillin to this fluid *For example* if an adult patient requires 2 litres of fluid in 24 hours and a daily dosage of 10 million units of penicillin add 5 million units to 1 litre and adjust the rate of flow so that the litre will be infused in 12 hours

3 *Intrapleural or Other Local Infusion* If fluid is aspirated give infusion in a volume equal to one quarter or one half the amount of fluid aspirated otherwise prepare as for intramuscular injection

Preparation of Solutions Solutions of penicillin should be prepared as follows Loosen powder Hold vial horizontally and rotate it *slowly* while directing the stream of diluent against the wall of the vial Shake vial vigorously after all the diluent has been added Depending on the route of administration use sterile pyrogen free distilled water (Sterile Water for Injection) sterile pyrogen free isotonic Sodium Chloride Injection or sterile pyrogen free 5% dextrose solution (Dextrose Injection)

Vial Content	*Desired Concentration*	*Add Diluent*
200 000 units	50 000 units/ml	4 ml
	100 000 units/ml	2 ml
	200 000 units/ml	1 ml
500 000 units	50 000 units/ml	9 8 ml
	100 000 units/ml	4 8 ml
	250 000 units/ml	1 8 ml
1 000 000 units	100 000 units/ml	9 6 ml
	200 000 units/ml	4 6 ml
	250 000 units/ml	3 6 ml

Dosage Dosage varies according to the site and severity of infection and the infecting organisms Suggested dosages are given in the following table Higher doses at more frequent intervals may be required when seriousness of infection and response to treatment indicate

In general when the infection has been brought under control and the patient is responding to treatment oral or repository parenteral penicillin preparations may be used in place of buffered penicillin G Therapy for most infections should be continued until signs of infection are absent and temperature has been normal for at least 48 hours Streptococcal infections should be treated for a total of 10 days to guard against the risk of rheumatic fever or glomerulonephritis Bacterial endocarditis should be treated for at least four to six weeks In some staphylococcal infections prolonged therapy is also required

GUIDE TO THERAPY

Condition	*Daily Dosage*	*Comments*
Severe infections caused by staphylococci (susceptible strains) streptococci pneumococci Clostridia (with antitoxin) C diphtheriae (with antitoxin) Complications of gonorrhoea	Total of 1 200 000 units to 12 000 000 units given in divided doses q 2 to 4 h im or by continuous iv drip	In staphylococcal infections higher dosage may be required sensitity tests should be made to determine efficacy of penicillin and/or other antibiotics Indicated surgical procedures should be carried out in all cases
Bacterial endocarditis Subacute pneumococcal or streptococcal	Total of 2 400 000 units given in divided doses q 4 h im or by continuous iv drip	Supplemental administration of streptomycin may be advisable in subacute bacterial endocarditis
Acute gonococcal or staphylococcal	Total of 24 000 000 units given in divided doses q 2 h im or by continuous iv drip	
Severe and/or due to resistant organisms	Total of 10 000 000 units to 100 000 000 units by continuous iv drip	
Syphilis Infantile congenital (for infants less than 2 years of age)	Total of 100 000 units per lb body weight given in divided doses q 3h im for 10 days	For other forms of syphilis use procaine penicillin

Presentation Vials of 200 000 units — Boxes of 25 vials
Vials of 500 000 units — Boxes of 25 vials
Vials of 1 000 000 units — Boxes of 25 vials

Expiration date 24 months The dry powder is relatively stable and may be stored at room temperature sterile solutions may be kept in the refrigerator for one week without significant loss of potency Store in a cool dry place

PENMYN® **Sterile Powder**

PENMYN® FORTIS **Sterile Powder**

Buffered Crystalline Sodium Penicillin G and Streptomycin Sulphate

Penmyn and Penmyn Fortis are supplied as dry powder for aqueous injection Each vial of Penmyn provides 500 000 units of Buffered Crystalline Sodium Penicillin G and Streptomycin Sulphate equivalent to 0 25 g of the base Each vial of Penmyn Fortis provides 500 000 units of Buffered Crystalline Sodium Penicillin G and Streptomycin Sulphate equivalent to 0 5 g of the base

Indications Penmyn and Penmyn Fortis are recommended in the treatment of peritonitis mediastinitis suspected brain abscess and other infections in which the causative organisms cannot be identified without unwarranted operative procedures Whenever possible however a thorough search for the primary focus should be made in order to determine if sensitivity to this combination warrants its use They are also recommended in some mixed infections particularly those involving gram positive and gram negative organisms e g those common in the respiratory or urogenital tract and in contaminated wounds Penmyn and Penmyn Fortis may be given for prophylaxis in surgery where there is danger of contamination particularly from the contents of hollow viscus They may also be valuable in selected cases of septicaemia caused by enterococci or other organisms susceptible to streptomycin and penicillin especially if there is *in vitro* evidence that this combination of antibiotics has an additive or synergistic effect When treatment is prolonged it is wise to perform periodic *in vitro* sensitivity tests to determine any change in the sensitivity of the causative organisms Penmyn and Penmyn Fortis may be effective in infections where the bacteria are relatively more resistant to penicillin or streptomycin alone than to the combination Penmyn will be of great value particularly in paediatric practice in view of its lower streptomycin content Children being more prone to streptomycin toxicity a dose of 20 to 40 mg of streptomycin per day per kg body weight should not be exceeded

Dosage The dose of Penmyn and Penmyn Fortis should be determined primarily by the currently recommended dosage of streptomycin The range of dosage is one to two vials of Penmyn or Penmyn Fortis per day In severe infection the dosage may be doubled In paediatric practice a dosage of 20 to 40 mg streptomycin per day per kg body weight will be the optimal range The best guide to the duration of treatment is provided by the clinical response of the patient It is recommended that treatment be continued for 3 to 4 days after the temperature has returned to normal or cultures have become consistently negative

Administration Following dilution in pyrogen free water or sterile isotonic sodium chloride solution Penmyn and Penmyn Fortis are administered intramuscularly For reconstitution add 1 1 ml of sterile distilled water or sterile normal saline to the vial of Penmyn 1 5 ml of diluent is to be used for Penmyn Fortis The administration is a matter of simple intramuscular injection after aspirating to be sure the needle is not in a vein Intramuscular injections are sometimes painful

The pain is reduced if the following precautions are observed

1 Inject high in the upper outer quadrant of the buttock
2 Change the site for each injection
3 Insert needle deeply to avoid subcutaneous deposition
4 Use 0.5% Xylocaine[§] as diluent for Penmyn and Penmyn Fortis if necessary

Toxicity There are two active components in Penmyn and Penmyn Fortis Penicillin and Streptomycin It has not been shown that any specific toxicity results from the simultaneous administration of penicillin and streptomycin

Penicillin Toxic reactions due to penicillin have been largely limited to sensitivity phenomena such as urticaria (hives) and angioneurotic oedema should be treated by the customary measures for combating allergy Antihistaminic drugs are beneficial Fever and arthralgia do not respond to such therapy but disappear on discontinuance of the drug If reactions cannot be controlled and are more serious than the condition being treated discontinue Penmyn

Streptomycin Streptomycin causes a number of untoward phenomena particularly injury to nervous system and hypersensitivity reactions With the usual dosage given for one or two weeks severe toxic effects are rarely produced The main danger in the chronic use of streptomycin is damage to the eighth cranial nerve manifested chiefly by vestibular disturbances and at times by auditory impairment Vestibular damage may be permanent although symptoms tend to disappear as the patient adjusts and learns to compensate visually Auditory impairment if it occurs also apears to be permanent

Skin or allergic reactions occur infrequently and can usually be controlled with antihistaminic agents

Headache paraesthesias of the face and gastric disturbances may occur Clinical judgement as to termination of therapy must be exercised when such side effects occur

Presentation Penmyn and Penmyn Fortis Vials of 1 dose boxes of 25 vials

Expiration date 24 months May be stored at room temperature Sterile solutions may be kept in the refrigerator for one week without loss of potency

§ Xylocaine is a trade mark of Astra Pharmaceutical Products Inc for Lidocaine

PENTIDS **Tablets**

Penicillin G Potassium 200 000 Units

PENTIDS® 400 **Tablets**

Penicillin G Potassium 400 000 Units

Pentids and Pentids 400 are scored compressed uncoated tablets for oral administration Each Pentids Tablet contains 125 mg (200 000 units) crystalline potassium penicillin G and each Pentids 400 Tablet contains 250 mg (400 000 units) Both are buffered with calcium carbonate

Action Studies conducted in human subjects indicate that following oral administration potassium penicillin G is readily absorbed from the gastrointestinal tract the desired elevated blood levels are achieved rapidly The efficacy of potassium penicillin G has been established by clinical studies in many millions of patients Pentids causes few gastrointestinal side effects hypersensitivity reactions following oral administration of penicillin are much less common than with parenteral use of the drug

Advantages

- economical
- readily absorbed from the gastrointestinal tract
- rapidly achieves desired blood levels
- few gastrointestinal side effects

Indications Pentids is indicated for the oral treatment of mild to moderately severe infections due to penicillin susceptible organisms including haemolytic streptococcal infections such as scarlet fever erysipelas tonsillitis and sinusitis lymphadenitis mastoiditis and otitis media minor infections due to susceptible staphylococci and without bacteraemia pneumococcal infections Vincent s stomatitis and pharyngitis and gonorrhoea Pentids may also be used for the prophylaxis of rheumatic fever If the infections do not respond promptly parenteral penicillin should be administered or other appropriate medication substituted In dentistry Pentids is indicated for the oral treatment of penicillin susceptible infections that may occur after tooth extraction or other dental surgery Pentids is useful as adjunctive therapy in pericoronitis alveolitis dentoalveolar abscess and cellulitis

Contraindications Like other oral penicillin preparations Pentids is not recommended in syphilis subacute bacterial endocarditis or meningitis and are contraindicated in individuals who have shown hypersensitivity to penicillin

Precautions As with any antibiotic preparation prolonged use may result in overgrowth of non susceptible organisms including fungi Constant observation of the patient is essential Should superinfection occur the drug should be discontinued and/or appropriate therapy instituted

Adverse Reactions Diarrhoea or epigastric distress is generally not a problem with oral penicillin therapy Loose stools may be encountered but this condition is usually less severe and certainly less frequent than with broad spectrum antibiotic therapy Untoward reactions are essentially limited to sensitivity phenomena Such reactions are less common with oral administration but may include urticaria serum sickness-like reactions (fever rash arthralgia) other skin rashes and rarely anaphylactoid shock They are more likely to occur in individuals with a history of allergy asthma hay fever or urticaria and in those who have previously demontrated hypersensitivity to penicillin

Urticarial serum sickness-like and other skin rash reactions may be controlled by antihistamines and if necessary corticosteroids Whenever such reactions occur penicillin should be discontinued unless in the opinion of the physician the condition being treated is life threatening and amenable only to penicillin therapy Serious anaphylactoid reactions are not controlled by antihistamines but require such measures as the immediate use of epinephrine oxygen intravenous corticosteroids and intravenous fluids

Dosage Penicillin dosage for children is not predicated on a weight basis but is the same as that for aqults The following dosage schedule is suggested

Haemolytic streptococcal infections scarlet fever erys pelas tonsillitis otitis media sinusitis pharyngitis lymphaden t s mastoiditis	400 000 units t i d T eatment should be continued for 10 full days to guard against the risk of rheumatic fever or glomcrulonephritis
Pyogenic skin infections Pneumococcal infections	200 000 or 400 000 units t i d
Minor staphylococcal infections (susceptible to o al therapy and with out bacteraemia)	400 000 units t i d in conjunction w th indicated surgical measures
Gonorrhoea	200 000 units t i d for 2 or 3 days When concomitant syph lis is suspected make darkfield examinations before treat ment and monthly serologic tests for a minimum of three months
Vincent s angina	200 000 units t i d
Prevention of streptococcal infections in individuals with a histo y of rheumatic fever	200 000 units once or twice daily for an indefinite period Twice daily is probably more effective

For maximum absorption of penicillin the dose should be given on an empty stomach Thus doses of 200 000 units should be given ½ hour before or at least 2 hours after meals The blood concentration with doses of 400 000 units is sufficientiy high to inhibit sensitive bacteria when the tablets are given without regard to meals but as can be expected the resultant concentration will be higher when they are given before meals

Presentation Pentids Strips of 6 tablets and boxes of 8 strips of 6 s
Pentids 400 Strips of 6 tablets and boxes of 8 strips of 6 s

Note Store in a cool dry place

Expiration date 24 months

PENTIDS® 800 — Tablets

Penicillin G Potassium 800 000 Units

Pentids 800 Tablets are scored compressed uncoated tablets for oral administration Each Pentids 800 Tablet contains 500 mg (800 000 units) crystalline potassium penicillin G It is buffered with calcium carbonate

Action Penicillin G is a bactericidal antibiotic Its batericidal action is exerted against penicillin sensitive microorganisms It is not active against penicillinase producing bacteria viz certain strains of staphylococci Following oral administration potassium penicillin G is readily absorbed from gastrointestinal tract Addition of buffer increases the stability of antibiotic n the gastric content Absorption occurs mainly in the duodenum and blood levels are achieved rapidly usually within a period of 30 to 60 minutes Fewer gastrointestinal side effects rapid absorption rapid achievement of desi ed blood levels and rare hypersensitivity reactions following oral administration are the main advantages of Pentids 800

Indications Pentids 800 Tablets are indicated for oral treatment of mild to moderately severe infections due to penicillin susceptible microorganisms These include haemolytic streptococcal infections such as scarlet fever erysipelas tonsillitis sinusitis lymphadenitis mastoiditis and otitis media infections due to susceptible strains of staphylococci without bacteraemia pneumococcal infections Vincent s stomatitis and pharyngitis and gonor rhoea Pentids 800 may also be used for the prophylaxis of streptococcal infections in individuals with a history of rheumatic fever and to prevent bacterial endocarditis in patients with congenital or rheumatic heart le sions who are to undergo dental surgery or other minor surgery

Contraindications It is contraindicated in patients with a history of hyper sensitivity to any penicillin

Precautions Prolonged use may result in superinfection Should superinfection occur the drug should be discontinued and/or appropriate therapy insti tuted

Adverse Reactions Loose stools may be encountered but this is less severe and less frequent than with broad spectrum antibiotics Other less frequent symptoms include nausea vomiting epigastric distress and black hairy tongue Untoward reactions are limited to sensitivity phenomena Such reactions are less common with oral administration Urticaria fever rash arthralgia and rarely anaphylactic shock may be encountered These are more likely to occur in individuals with a history of allergy and in those patients who have previously demonstrated hypersensitivity to penicillin Whenever severe hypersensitivity reactions occur penicillin therapy should be discontinued and appropriate therapy instituted

Dosage Severity of the infection therapeutic response and the sensitivity of causative organisms are the primary criteria by which the dosage of Pentids 800 is established in treatment of individual patient For mild to moderately severe streptococcal infections of the upper respiratory tract and including otitis media scarlet fever and mild erysipelas one tablet may be given two times daily for ten days For other infections one to two tablets of Pentids 800 given twice daily will usually suffice Alternatively one tablet may be given t d

For medical conditions in which oral penicillin therapy is indicated as a pro phylaxis $^1/_2$ tablet may be given on a continuing basis for prevention of recurrence of rheumatic fever and/or chorea

To prevent bacterial endocarditis in patients with congenital or rheumatic heart lesions who are to undergo dental procedure or other minor surgery

or instrumentation ½ tablet given on day of procedure 500 000 units aqueous penicillin G instramuscular an hour prior to procedure and half tablet t i d for two more days will suffice

Presentation Pentids 800 Strips of 4 tablets and boxes of 12 strips of 4 s

Note Store in a cool dry place

Expiration date 24 months

PENTIDS® FOR SYRUP — Powder for Syrup

Penicillin G Potassium

Pentids for Syrup is penicillin G potassium for infants and children Each 5 ml contains 125 mg (200 000 units) crystalline potassium penicillin G buffered with sodium phosphates

Action Following oral administration potassium penicillin G is readily absorbed from the gastrointestinal tract Addition of buffer material increases the stability of the antibiotic in the gastric content Absorption occurs mainly in the duodenum and the desired elevated blood levels are achieved rapidly within a period of 30 to 60 minutes Excretion occurs mainly through the kidney Approximately 60% of penicillin G is bound to serum proteins The drug is widely distributed through the body tissues in varying amounts Penicillin G penetrates into all other tissues with very limited amounts found in the cerebrospinal fluid

Penicillin G is bactericidal against penicillin sensitive microorganisms It is not active against the penicillinase producing bacteria viz some strains of staphylococci

Advantages

- economical
- readily absorbed from the gastrointestinal tract
- rapidly achieves desired blood levels
- few gastrointestinal side effects

Indications Pentids for Syrup is indicated in the treatment of mild to moderate ly severe infections due to penicillin G sensitive microorganisms Therapy should be guided by bacteriological studies including sensitivity tests and clinical response The susceptible organisms which will respond to ade quate dosage of Pentids for Syrup include Streptococcal Group A infec tions of upper respiratory tract skin and soft tissues scarlet fever mild ery sipelas pneumococcal infections of the respiratory tract staphylococcal infections of the skin and soft tissues excluding penicillinase-producing strains Vincent s gingivitis and pharyngitis

Pentids for Syrup can also be employed for prophylaxis against recurrence following rheumatic fever and chorea to prevent bacterial endocarditis in patients with congenital and/or rheumatic heart lesions who are to under go dental procedures or other minor surgery such as tonsillectomy sinus puncture or instrumentation such as laryngoscopy bronchoscopy or catheterization

Contraindications It is contraindicated in patients with a history of hypersensitivity to any penicillin

Warning Severe pneumonia empyema bacteraemia pericarditis meningitis bacterial endocarditis and septic arthritis should not be treated with oral penicillin G during the acute stage

Precautions Prolonged use in some cases may result in overgrowth of nonsusceptible organisms including fungi Should superinfection occur the drug should be discontinued and/or appropriate therapy instituted The use of Pentids for Syrup cannot be relied upon in patients with severe illness or with nausea vomiting gastric dilatation and intestinal hypermotility With prolonged therapy with penicillin and particularly with high dosage schedule periodic evaluation of renal and haematopoietic systems is recommended

Adverse Reactions Serious and occasional fatal hypersensitivity reactions have been reported in patients on penicillin therapy Although these are much less frequent with Pentids for Syrup this hazard has to be borne in mind Cross hypersensitivity with cephalosporins has also been observed Other allergic reactions like serum sickness and urticaria have been reported more in such patients with history of allergy asthma and hay fever In such cases the syrup should be discontinued and appropriate therapy instituted Loose stools may be encountered in a few cases Other less frequent symptoms include nausea vomiting epigastric distress and black hairy tongue

Administration and Dosage Therapy for children under 12 years of age is calculated on the basis of body weight For infants and small children the suggested dose is 15 56 mg (25 000 90 000 units) per kg/day in 3 to 6 divided doses It should be given at least 1 to 2 hours after meals

For mild streptococcal infections 5 ml of Pentids for Syrup containing 200 000 units t i d for 10 days is recommended while for moderate to severe infections a higher dose of 10 ml (400 000 units) may be employed t i d For mild to moderate pneumococcal infections of the respiratory tract 10 ml (400 000 units) t i d of Pentids for Syrup till two days after the fever has touched normal is the usual course of treatment 5 ml to 10 ml of Pentids for Syrup t i d is advisable for staphylococcal infections of skin and soft tissues Vincent s gingivitis and pharyngitis until infection is cured

For medical prophylaxis against recurrence following rheumatic fever and/or chorea 5 ml twice daily on a continuing basis is advocated To prevent bacterial endocarditis in patients with congenital or rheumatic heart lesions who are to undergo dental procedures or minor upper respiratory tract surgery or instrumentation 5 ml of Pentids for Syrup is given every 6 hours for 2 days prior to surgery on the day of operation and for 2 days afterwards In addition to this an intramuscular injection of 600 000 units of aqueous penicillin G is given one hour prior to the procedure

Directions for preparing the syrup A cup to measure 27 ml of water has been provided with this pack Fill this cup with boiled and cooled water add it to the contents and shake well This will make the final volume of syrup to 60 ml One spoon enclosed will measure 5 ml containing 125 mg

(200 000 units) of potassium penicillin G Total volume of syrup provides 12 doses each containing 200 000 units of potassium penicillin G

Presentation Pentids for Syrup is available for oral administration as powder which when reconstituted as directed provides 60 ml of fruit-flavoured syrup Each 5 ml (measuring spoon) contains 125 mg (200 000 units) of potassium penicillin G One such bottle of reconstituted syrup provides in all 12 doses

Note Reconstituted material should be used up within 3 days Store dry powder in a cool dry place

Expiration date 18 months

PHOSFOMIN‡ Elixir

Multiple Glycerophosphates Elixir with B Complex Vitamins

Phosfomin is Multiple Glycerophosphates Elixir with B Complex Vitamins

Each 15 ml of pleasantly flavoured Phosfomin provides

Calcium Glycerophosphate	110 mg
Sodium Glycerophosphate	80 mg
Potassium Glycerophosphate	20 mg
Manganese Glycerophosphate	10 mg
Vitamin B_1 (Thiamine Mononitrate)	2 mg
Vitamin B_2 (Riboflavine)	1 mg
Vitamin B_6 (Pyridoxine Hydrochloride)	0 5 mg
Niacinamide	15 mg
d Panthenol	1 mg
Vitamin B_{12}	15 mcg
Alcohol	1 75 ml

Extra Vitamins added to compensate for loss on storage
Alcohol content 11% by volume

Indications Phosfomin combines certain B Complex vitamins which stimulate general metabolism and appetite with glycerophosphates which have been in use for some years as a tonic stimulant Phosfomin improves appetite and digestive functions tends to correct B Complex deficiencies and also increases and improves the general physical well being of the patient

Dosage One tablespoonful (15 ml) two times a day

Presentation Bottles of 240 ml and 480 ml

Note Bottles of Phosfomin should be kept tightly closed they should not be exposed to sunlight

Expiration date 24 months

PHOSFOMIN‡ IRON — Elixir

Multiple Glycerophosphates Elixir with B Complex Vitamins and Iron

Phosfomin Iron is Multiple Glycerophosphates Elixir with B Complex Vitamins and Iron

Each 15 ml of pleasantly-flavoured Phosfomin Iron provides

Calcium Glycerophosphate	110 mg
Sodium Glycerophosphate	80 mg
Potassium Glycerophosphate	20 mg
Manganese Glycerophosphate	10 mg
Ferric Ammonium Citrate	46.5 mg
Vitamin B_1 (Thiamine Mononitrate)	2 mg
Vitamin B_2 (Riboflavine)	1 mg
Vitamin B_6 (Pyridoxine Hydrochloride)	0.5 mg
Niacinamide	15 mg
d Panthenol	1 mg
Vitamin B_{12}	15 mcg
Alcohol	1.75 ml

Extra Vitamins added to compensate for loss on storage
Alcohol content 11% by volume

Indications Phosfomin Iron combines multiple glycerophosphates B Complex vitamins and Iron which are essential for the general well being of the patient It improves appetite and digestive functions stimulates general metabolism and corrects certain B Complex deficiencies Supplementary iron in Phosfomin Iron tends to compensate iron loss in women during menstruation and other physiological stressful conditions

Dosage One tablespoonful (15 ml) two times a day

Presentation Bottles of 240 ml and 480 ml

Note Bottles of Phosfomin Iron should be kept tightly closed they should not be exposed to sunlight

Expiration date 24 months

PROMOLAN‡ — Powder

High Protein Food Fortified with Carbohydrates Vitamins Minerals and Lysine

Promolan is a comprehensive high protein supplement containing essential vitamins minerals and lysine

Each 30 g Promolan provides

Protein	12 g
Carbohydrate	10 g
VITAMINS	
Vitamin A	2500 I U
Vitamin D	200 I U
Vitamin C	60 mg
Niacinamide	20 mg
Vitamin B_1	3 mg
Calcium Pantothenate	3 mg
Vitamin B_2	2 5 mg
Folic Acid	0 5 mg
Vitamin E	0 4 mg
Vitamin B_6	0 25 mg
Menadione	0 13 mg
Vitamin B_{12}	3 mcg
MINERALS	
Calcium Lactate	780 mg
Ferrous Gluconate	17 mg
Potassium (as Carbonate)	15 mg
Copper (as Sulphate)	0 5 mg
Magnesium (as Carbonate)	0 5 mg
Zinc (as Sulphate)	0 25 mg
Iodine (asPotassium Iodide)	0 05 mg
Manganese (as Glycerophosphate)	0 05 mg
OTHERS	
Lysine	100 mg
Inositol	25 mg

Promolan provides soya beans protein which contains all the essential amino acids necessary for tissue maintenance repair and growth Promolan also provides essential vitamins and minerals which are important for proper nutrition Soya protein has an additional beneficial property of lowering cholesterol in blood Promolan is fortified with lysine – an amino acid which promotes growth Promolan contains carbohydrates which spare proteins for anabolic processes Promolan is therefore a versatile high protein supplement

Advantages

- Promolan has pleasant taste and it is easily digestible
- It provides adequate proteins and is fortified with lysine
- Soya proteins have additional advantage in lowering cholesterol
- Vitamins and minerals present in Promolan supplement nutritional re quirements

Indications

Promolan helps in overcoming debility fatigue and exhaustion during convalescence

Promolan provides an excellent protein supplement for patients
a) Immobilized for prolonged period due to fractures heart disease and following surgical operations etc
b) In liver diseases viz Cirrhosis of liver
c) In kidney diseases viz Nephrosis
d) In malnutrition and oedema due to hypoproteinaemia
e) In lung diseases viz Bronchiectasis Pulmonary tuberculosis etc
f) In certain gastrointestinal diseases viz Protein losing enteropathy etc
g) Burns

Promolan provides an excellent protein supplement for increased demand
a) Pregnancy and lactation
b) Children during the growing period

Promolan provides proteins vitamins and minerals during convalescence
a) Following a major illness
b) Postoperative period

Promolan provides a low roughage diet in
a) Enteric fever
b) Ulcers
c) Colitis
d) Following gastrointestinal surgery

Promolan provides protein and other essential ingredients of diet in
a) Malnutrition due to worm infestation (following specific therapy)
b) Tropical and nontropical sprue

Promolan provides proteins vitamins and minerals under special conditions
a) Lack of appetite
b) Geriatric cases
c) Fastidious food habits

Direction for use Two heaped tablespoonfuls (approx 30 g) may be taken 2 to 3 times a day between meals and at bedtime

Mix two heaped tablespoonfuls of Promolan with a little milk or water to make a paste Add more milk or water to make a full cup Sugar may be added for taste Mixing Promolan with very hot liquids is not advisable

Presentation Promolan is available as pleasant tasting chocolate flavoured powder in tins of 225 g

Expiration date 18 months

PRONESTYL® HYDROCHLORIDE — Parenteral Solution Tablets

Procainamide Hydrochloride

Pronestyl is the amide analogue of procaine hydrochloride It is available as a 10% sterile aqueous solution (100 mg/ml) for parenteral use and as tablets supplying 0 25 g for oral use

The parenteral solution contains 0 9% (w/v) benzyl alcohol and 0 1% sodium metabisulphite as preservatives the pH has been adjusted to 4 0-6 0 with hydrochloric acid or sodium hydroxide The solution which is colour-

less initially may in time develop a slightly yellow colour This does not indicate a change which would prevent its use but a solution darker than light amber or discoloured in any other way should not be used At the time of manufacture the air in the container is replaced by nitrogen

Action Procainamide depresses the excitability of cardiac muscle to electrical stimulation and slows conduction in the atrium the bundle of His and the ventricle The refractory period of the atrium is considerably more p o longed than that of the ventricle Contractility of the heart is usually not affected nor is cardiac output decreased to any extent unless myocardial damage exists In the absence of any arrhythmia the heart rate may occa sionally be accelerated by conventional doses suggesting that the drug possesses anticholinergic properties Larger doses can induce atrioventri cular block and ventricular extrasystoles which may proceed to ventricular fibrillation These effects on the myocardium are reflected in the electrocar diogram a widening of the QRS complex occurs most consistently less regularly the P R and Q T intervals are prolonged and the QRS and T waves show some decrease in voltage

The action of procainamide begins almost immediately after intramuscular or intravenous administration Plasma levels after intramuscular injection are at their peak in 15 to 60 minutes Following oral administration plasma levels of the drug are comparable to those obtained parenterally and are maximal within an hour therapeutic levels are usually attained in half that time

Procainamide is less readily hydrolyzed than procaine and plasma levels decline slowly- about 10% to 20% per hour The drug is excreted primarily in the urine about 10% as free and conjugated p aminobenzoic acid and about 60% in the unchanged form The fate of the remainder is unknown

Indications Pronestyl Injection (Procainamide Hydrochloride Injection) is indi cated in the treatment of ventricular extrasystoles and tachycardia atrial fibrillation paroxysmal atrial tachycardia and cardiac arrhythmias asso ciated with anaesthesia and surgery

Pronestyl Tablets (Procainamide Hydrochloride Tablets) are indicated in the treatment of premature ventricular contractions and ventricular tachy cardia atrial fibrillation and paroxysmal atrial tachycardia

Contraindications It has been suggested that procainamide be contraindicat ed in patients with myasthenia gravis Hypersensitivity to the drug is an absolute contraindication in this connection cross sensitivity to procaine and related drugs must be borne in mind Procainamide should not be administered to patients with complete atrioventricular heart block Procainamide is also contraindicated in cases of second degree and third degree A V block unless an electrical pacemaker is operative

Precautions During administration of the drug evidence of untoward myo- cardial responses should be carefully watched for in all patients In the pre sence of an abnormal myocardium procainamide may at times produce untoward responses In atrial fibrillation or flutter the ventricular rate may increase suddenly as the atrial rate is slowed Adequate digitalization reduces but does not abolish this danger If myocardial damage exists ventricular tachycardia is particularly hazardous Correction of atrial fibrilla

tion with resultant forceful contractions of the atrium may cause a dis lodgement of mural thrombi and produce an embolic episode However it has been suggested that in a patient who is already discharging emboli procainamide is more likely to stop than to aggravate the process

Attempts to adjust the heart rate in a patient who has developed ventricular tachycardia during an occlusive coronary episode should be carried out with extreme caution Caution is also required in marked disturbances of atrioventricular conduction such as A V block bundle branch block or severe digitalis intoxication where the use of procainamide may result in additional depression of conduction and ventricular asystole or fibrillation

Parenteral administration should be monitored electrocardiographically whenever practicable If electrocardiograms give evidence of impending heart block parenteral administration should be discontinued at once Since patients with severe organic heart disease and ventricular tachycardia may also have complete heart block which is difficult to diagnose under these circumstances this complication should always be kept in mind when treating ventricular arrhythmias with procainamide (especially parenterally) If the ventricular rate is significantly slowed by procainamide without attainment of regular atrioventricular conduction the drug should be stopped and the patient re evaluated as asystole may result under these circumstances

In patients receiving normal dosage but who have both liver and kidney disease symptoms of overdosage (principally ventricular bradycardia and severe hypotension) may occur due to drug accumulation

Instances of a syndrome resembling lupus erythematosus have been reported in connection with oral maintenance procainamide therapy The mechanism of this syndrome is uncertain Polyarthralgia arthritis and pleuritic pain are common symptoms to a lesser extent fever myalgia skin lesions pleural effusion and pericarditis may occur Rare cases of thrombocytopenia or Coombs positive haemolytic anaemia have been reported which may be related to this syndrome Patients receiving procainamide for extended periods of time or in whom symptoms suggestive of a lupus like reaction appear should have antinuclear antibody titres measured at regular intervals The drug should be discontinued if there is a rising titre (antinuclear antibody) or clinical symptoms of LE appear The LE syndrome may be reversible upon discontinuation of the drug If discontinuation of the drug does not cause remission of the symptoms steroid therapy may be effective If the syndrome develops in a patient with recurrent life threatening arrythmias not controllable by other antiarrythmic agents steroid suppressive therapy may be used concomitantly with procainamide

Adverse Reactions Because procainamide is a peripheral vasodilator intravenous administration may produce transient but at times severe lowering of blood pressure particularly in conscious patients Intramuscular injection is less likely to be accompanied by serious falls in blood pressure and hypotension following oral administration is rare Serious disturbances of cardiac rhythm such as ventricular asystole or fibrillation are also more common with intravenous administration Precautionary measures to be followed during intravenous administration are given in the section on *Administration and Dosage*

Large oral doses of procainamide may sometimes produce anorexia nausea urticaria and/or pruritus

A syndrome resembling lupus erythematosus has been reported (See *Pre cautions*) Reactions consisting of fever and chills have been reported including a case with fever and chills plus nausea vomiting abdominal pain acute hepatomegaly and a rise in serum glutamic oxaloacet c trans aminase following single doses of the drug Bitter taste diarrhoea weakness mental depression giddiness and psychosis with hallucina tions have been reported The possibility of such untoward effects should be borne in mind

Hypersensitivity reactions such angioneurotic oedema and maculopapular rash have also occurred

Agranulocytosis has occasionally followed the repeated use of the drug and deaths have occurred Therefore routine blood counts are advisable during maintenance procainamide therapy The patients should be ins tructed to report any soreness of the mouth throat or gums unexplained fever or any symptoms of upper respiratory tract infections If any of these should occur and leucocyte counts indicate cellular depression procaina mide therapy should be discontinued and appropriate treatment should be instituted immediately

Administration and Dosage Oral administration is preferred When parenteral therapy is necessay intramuscular administration is the method of choice *Intravenous use should be limited to extreme emergencies*

If procainamide therapy is continued for appreciable periods electrocardio grams should be taken occasionally to determine the need for the drug

Oral dose For ventricular tachycardia an initial dose of 1 g orally followed thereafter by a *total daily dose* of 50 mg/kg of body weight given at 3 hour intervals The suggested oral dosage for premature ventricular contrac tions is 50 mg/kg of body weight daily given in divided doses at 3 hour intervals

To provide 50 mg/kg/day Give patients weighing less than 120 lbs 250 mg q 3 hours give patients between 120 and 200 lbs 375 mg q 3 hours and give patients over 200 lbs 500 mg q 3 hours This dosage schedule is for use as a guide for treating patient but all patients must be considered on an individual basis

In atrial fibrillation and paroxysmal atrial tachycardia an initial dose of 1 25 g may be followed in one hour by 0 75 g if there have been no electro cardiographic changes A dose of 0 5 to 1 g may then be given every 2 hours until arrhythmia is interrupted or the limit of tolerance is reached Suggested maintenance dosage is 0 5 to 1 g every 4 to 6 hours

Intramuscular dose If the oral route is not feasible 0 5 to 1 g may be given intramuscularly repeated every 6 hours until oral therapy is possible

Intravenous dose The usual intravenous dose for ventricular extrasystoles and tachycardia ranges from 0 2 to 1 g for atrial fibrillation and paroxysmal atrial tachycardia the intravenous dose averages 0 5 g although up to 1 g may be required

Caution Intravenous use of procainamide is accompanied by a hypotensive response sometimes precipitous For this reason the intravenous dose should not exceed 1 g and should be diluted to permit greater control of infusion rate It should be administered at a rate not exceeding 25 to 50 mg per minute Intravenous infusion should be monitored electrocardiographically so that the infusion may be stopped when the arrhythmia is interrupted or when excessive widening of the QRS complex or prolongation of the P R interval suggests the occurrence of myocardial toxicity Patients should be kept in a supine position and blood pressure should be measured almost continuously during the infusion If the fall in blood pressure exceeds 15 mm Hg the infusion should be temporarily discontinued Solutions of Phenylephrine Hydrochloride Injection should be available to counteract severe hypotensive responses

Surgical Use For cardiac arrhythmias associated with anaesthesia and surgery the suggested parenteral dose is 0 1 to 0 5 g preferably given intramuscularly

Presentation Tablets 0 25 g bottles of 25

Expiration date 24 months for Pronestyl Tablets

Parenteral Solution 100 mg per ml vials of 10 ml

Expiration date 12 months for Pronestyl Injection

QUIXALIN®

Tablets

Halquinol

Quixalin Tablets provide Halquinol (chlorhydroxyquinoline) in tablet form for oral administration in the treatment of certain alimentary tract infections Each Quixalin Tablet contains 0 25 g of Halquinol

Action Quixalin has been found to exhibit a high order of activity against a wide variety of organisms commonly responsible for enteric infections including both gram positive and gram negative bacteria many fungi and certain protozoa [12] When tested *in vitro* Quixalin was found to show a markedly greater inhibitory activity than other halogenated oxines against such common enteric bacilli as *Salmonella* (various species) *Shigella* (various species) *Escherichia coli* as well as *Proteus vulgaris Staphylococcus aureus Streptococcus faecalis* and *Streptococcus bovis* When tested against fungi Quixalin proved to have a relatively wide range of antifungal activity showing an inhibitory effect on *Candida albicans* Epidermophyton floccosum *Tricophyton mentagrophytes* several *Microsporum* species and several *Aspergillus* species Quixalin has a direct inhibitory effect on *Entamoeba histolytica in vitro*

Excellent clinical results have been obtained with Quixalin in many common bacterial and amoebic bowel infections in patients of all age groups After oral administration of Quixalin the faeces become more solid the bowel movements less frequent and tenesmus is diminished within a few days In most cases clinical and microbiological cure can be expected The

drug is well tolerated In the rare instances when side effects occur these are mild and minor in nature

Indications Quixalin Tablets are indicated in the treatment of intestinal amoebiasis bacillary dysentery and non specific diarrhoea i e diarrhoeal conditions fo which the causative organisms have not been identified

If specific diagnosis has not yet been made and the patient shows no improvement after 24 hours on the recommended dosage identification of the causative organisms may be necessary for the consideration of additional therapeutic measures

Advantages

- combats all three main groups of diarrhoea i e amoebic bacterial and non specific
- tolerance is excellent
- no specific contraindications
- side reactions are minor and rare
- no danger of gastric irritation or kidney or liver damage as with iodine or arsenic compounds

Dosage and Administration For adults 1-2 tablets (0 25 0 5 g) given 3 or 4 times daily are usually adequate Higher dosages up to a daily total of 12 to 16 tablets (3 to 4 g) in divided doses may be required when symptoms are severe or of long duration

Treatment of intestinal amoebiasis should be continued for 14 days In certain cases of intestinal amoebiasis two courses of treatment may be necessary

In children weighing up to 40 kg the recommended total daily dose is 30 to 50 mg per kg of body weight in 3 or 4 divided doses depending on the severity of the infection The total adult dose of 1 5 to 2 0 g in 3 or 4 divided doses may be administered to children weighing 40 kg or more Duration of treatment depends upon the disease entity being treated but should not exceed 14 days for any one course of treatment

Side Effects and Precautions The only undesirable reactions that have occurred with Quixalin Tablets have been few instances of nausea and a mild rash in few patients suggestive of possible sensitivity

In children under 2 years of age diarrhoea may cause rapid and profound changes in water and electrolyte balance The administration of drugs in these circumstances requires overall evaluation of the patient with particular attention to excretory mechanism Correction of water and electrolyte balance may be of primary concern

Relatively prolonged and uninterrupted treatment with halogenated hydroxy quinoline derivatives used in high dosage for more than 14 days have been reported to cause peripheral neuritis and damage to the optic nerves in isolated cases

Contraindications There are no known contraindications Quixalin however is not recommended in typhoid fever severe fulminating bacillary dysentery or systemic infections

Presentation Strips of 10 tablets and boxes of 50 strips of 10 s

References 1 Heseltine WW and Campbell PJ Laboratory Studies on Chlorhydroxyquinoline J Trop Med 63 (1960)
2 Neogy K N and Nandy P K Spectrum of Activity of Quixalin against Enteropathogenic Bacteria Bull Calcutta Sch Trop Med 13 131 (1965)

RAUDIXIN® — Tablets

Standardized Whole Root Rauwolfia Serpentina

Raudixin is Standardized Rauwolfia Serpentina Whole Root an antihypertensive agent prepared from the powdered whole root of *Rauwolfia serpentina* Benth It is standardized by pharmacognostic chemical and biological tests

Action Raudixin exerts the aggregate action of all the alkaloids contained in the whole *Rauwolfia serpentina* root Thus its therapeutic effect exceeds that of any single alkaloid from the root For instance in the rat dog and monkey Raudixin has a hypotensive-tranquillizing action two to three times that accounted for by its reserpine content In man the antihypertensive effect of 250 mg Raudixin is equivalent to that of 1 mg reserpine yet 250 mg whole root contains only about 0 25 mg reserpine by weight

Raudixin has three basic pharmacologic actions i e antihypertensive tranquillizing and bradycardic Generally bradycardia is the first response to therapy as shown by a lowered pulse rate The antihypertensive and tranquillizing effects develop more slowly over a period of one to three weeks and may continue for a week or more after the drug is discontinued

In hypertension Raudixin produces a gradual sustained lowering of blood pressure but does not significantly affect normal blood pressure The gradual antihypertensive action gives patients time to adjust smoothly to new lower blood pressure levels without distressing episodes of dizziness or weakness due to sudden sharp drops in pressure Further the sustained antihypertensive action is an added advantage for hypertensive patients who occasionally skip a dose an accidentally omitted dose is not followed by a sudden dangerous rise in blood pressure

Due to its tranquillizing action Raudixin is valuable in the management of anxiety and tension states and particularly effective in neurogenic hypertension i e essential hypertension with the emotional component predominating This tranquillizing effect affords relief of such common hypertensive symptoms as anxiety tension headache insomnia and palpitations patients generally experience a sense of well being without lethargy The bradycardic effect of Raudixin reduces the work load of the heart helping to increase cardiac efficiency Although generally mild the bradycardic effect may be marked in the hypertensive with tachycardia in whom the drug may reduce the heart rate to normal

Advantages

- effective antihypertensive action
- gradual antihypertensive action which lets patients adjust smoothly to new lower blood pressure levels

- sustained antihypertensive action which protects patients who occasionally skip a dose by accident
- complementary antihypertensive action when used with other antihypertensive agents
- effective tranquillization for management of anxiety and tension states and for helping relieve emotional aspects of hypertension
- bradycardia to increase cardiac efficiency
- few serious gastrointestinal side effects
- no habituation (tolerance not reported)
- long term safety (has been given continuously for years)
- meticulous standardization for consistent predictable results

Indications

In Hypertension Raudixin alone is frequently sufficient in mild to moderate hypertension It is the antihypertensive agent of choice when the emotional component is the predominant factor Many clinicians prefer its gradual gentle action since hypertensive patients particularly the elderly do not tolerate sudden changes in blood pressure well

When an additional antihypertensive effect is needed combination therapy is recommended such as that provided by Di Raudixin® (Rauwolfia Serpentina Whole Root (Raudixin) and Hydroflumethiazide) Raudixin may also be used in conjunction with a suitable diuretic or other antihypertensive agent e g hydralazine ganglionic blocking agents or guanethidine

As a Tranquillizing Agent Raudixin is indicated in the management of anxiety and tension states and other conditions characterized by nervousness irritability excitability and insomnia The drug is of value in certain compulsive and other behaviour disorders In addition it is useful as adjunctive therapy in a number of disorders with emotional overlay such as certain dermotoses tension headache some menopausal symptoms and chronic insomnia The drug is also worthy of trial in the management of hyperirritable and hypertonic children in the control of enuresis and in behaviour problems

Adverse Reactions and Precautions Rauwolfia preparations are known to cause diarrhoea weight gain nausea and vomiting drowsiness nasal stuffiness reversible extrapyramidal tract symptoms bizarre dreams emotional depression and anxiety Like any preparation containing Rauwolfia or its alkaloids Raudixin should be administered with caution to patients with a history of depression or suicidal tendencies Patients exhibiting signs of depression should be placed on lower dosage or the drug should be discontinued

Patients on high dosage should be observed carefully at regular intervals to detect possible reactivation of peptic ulcer

Since some patients receiving Rauwolfia preparations nave experienced marked hypotension under surgical anaesthesia it may be advisable to discontinue therapy for a period of about 2 weeks prior to elective surgery Emergency surgery may be done by using anticholinergic or adrenergic drugs if necessary to prevent vagal circulatory responses other supportive measures may be used as indicated

Water retention with oedema in patients with hypertensive vascular disease occurs rarely but it generally clears with cessation of therapy or with the administration of a diuretic agent such as Di Ademil® (Hydroflumethiazide)

Administration and Dosage

Management of Hypertension Raudixin does not require the continual and often difficult adjustment of dosage common to other hypotensive agents Adult patients may be started on a dose of 200 mg daily given as a single dose or divided and given morning and evening

The full antihypertensive effect may not be seen for one to three weeks Adjustments in dosage should be made after the full effect of the drug has occurred Maintenance dosage may range from 50 to 300 mg per day given as a single dose or as two divided doses Some patients on maintenance therapy require much smaller doses while others do better with larger doses Dosage may be increased if there are no complaints of side effects and if the antihypertensive effect is insufficient Dosage should be reduced if undesirable side effects appear Raudixin is given continuously not in interrupted courses of therapy In contrast to other antihypertensive agents frequent observation of blood pressure is not required since postural syncope is not a problem

The same dosage regimen is recommended when Raudixin is combined with other antihypertensive drugs However concomitant use with ganglionic blocking agents hydralazine or guanethidine necessitates an immediate dosage reduction by at least 50% of the other more toxic agents thus minimizing the incidence and severity of their side effects

Management of Emotional Disorders In adults the anxious patient or the patient with physical symptoms complicated by emotional factors dosage may start with 200 mg daily given as a single or divided dose Dosage may be adjusted upward or downward depending upon the degree of tranquillization achieved In adjusting dosage it is important to take into account the fact that results of therapy tend to appear slowly Maintenance doses may vary from 50 to 300 mg per day given as a single dose or as two divided doses

Note Dosage for adolescents children and the aged should be proportionately less than the usual adult dosage

Presentation Coated tablets 100 mg bottles of 25 and 100

RECLOR® 250 mg **Capsules**

RECLOR® 500 mg **Capsules**

Chloramphenicol

Reclor is chloramphenicol available as capsules providing 250 mg and 500 mg

Action Chloramphenicol is an antibiotic produced by the soil mould *Strepto*

myces venezuelae and it can also be prepared synthetically It inhibits the growth of a wide range of gram positive and gram negative bacteria rickettsiae and viruses

Indications Reclor is the drug of choice in the treatment of typhoid fever and Haemophilus influenzae infection Reclor is of value in typhus Rocky Mountain spotted fever lymphogranuloma venereum primary atypical pneumonia psittacosis Salmonella and Shigella infections and bacillary urinary infections especially when the causative organisms are resistant to the commonly used tetracycline group of broad spectrum antibiotics or other antibiotics

Dosage The suggested adult dose for chloramphenicol is 1 5 to 3 g per day in divided doses In typhoid fever 3 g per day can be given in divided doses This dose may be continued until the patient becomes afebrile Thereafter the dosage can be reduced and continued further for one or two weeks Longer treatment may be desirable in severe cases to decrease the incidence of relapse

Warning Blood dyscrasias have occurred after both short term and prolonged therapy with chloramphenicol Serious and even fatal dyscrasias (aplastic anaemia hypoplastic anaemia thrombocytopenia granulocytopenia) are known to occur after the administration of chloramphenicol Bearing in mind the possibility that such reactions may occur chloramphenicol should be used only for serious infections caused by organisms which are susceptible to its antibacterial effects Chloramphenicol should not be used when other less potentially dangerous agents will be effective or in the treatment of trivial infections such as cold influenza or viral infections of the throat or as a prophylactic

Precautions It is essential that adequate blood studies be done during treatment with the drug While blood studies may detect early peripheral blood changes such as leucopenia or granulocytopenia before they become irreversible such studies cannot be relied upon to detect bone marrow depression prior to development of aplastic anaemia

Precaution Reclor 250 mg Capsules Strips of 12 capsules and boxes of 8 strips of 12 s

Reclor 500 mg Capsules Strips of 12 capsules and boxes of 4 strips of 12 s

Expiration date 24 months

RECLOR® SUSPENSION — Oral Suspension

Chloramphenicol

Reclor Suspension (Chloramphenicol) is a ready made flavoured aqueous suspension of chloramphenicol palmitate Each 5 ml of Reclor Suspension provides chloramphenicol palmitate equivalent to 125 mg of chloramphenicol

Action Chloramphenicol is an antibiotic produced by the soil mould *Streptomyces venezuelae* and it can also be prepared synthetically It inhibits the

growth of a wide range of gram positive and gram negative bacteria rickettsiae and viruses

Indications Reclor Suspension is the drug of choice in the treatment of typhoid fever and Haemophilus influenzae infection Reclor Suspension is of value in typhus Rocky Mountain spotted fever lymphogranuloma venereum primary atypical pneumonia psittacosis Salmonella and Shigellae infections and bacillary urinary infections especially when the causative organisms are resistant to the commonly used tetracycline group of broad spectrum antibiotics or other antibiotics

Warning Blood dyscrasias have occurred after both short term and prolonged therapy with chloramphenicol Serious and even fatal dyscrasias (aplastic anaemia hypoplastic anaemia thrombocytopenia granulocytopenia) are known to occur after the administration of chloramphenicol Bearing in mind the possibility that such reactions may occur chloramphenicol should be used only for serious infections caused by organisms which are susceptible to its antibacterial effects Chloramphenicol should not be used when other less potentially dangerous agents will be effective or in the treatment of trivial infections such as cold influenza or viral infections of the throat or as a prophylactic

Precautions It is essential that adequate blood studies be done during treatment with the drug While blood studies may detect early peripheral blood changes such as leucopenia or granulocytopenia before they become irreversible such studies cannot be relied upon to detect bone marrow depression prior to development of aplastic anaemia

Dosage The dose for children should be calculated as 25 50 mg per kg of body weight per day and given in divided doses Since neonates are unable to conjugate and excrete the antibiotic effectively a dose up to 25 mg per kg of body weight per day in four equal doses at six-hour intervals usually produces and maintains adequate concentrations in blood and tissues to control most infections for which the drug is indicated In infants with serious infection a dose as high as 50 mg per kg per day may be given during the acute stage of the illness but should be reduced to 25 mg per day as soon improvement occurs Older children with severe infections may require a dose up to 100 mg per kg per day however it is recommended that the dose be reduced to 50 mg per kg per day as soon as possible

Presentation Reclor Suspension is available in bottles of 60 ml Each 5 ml of suspension provides chloramphenicol palmitate equivalent to 125 mg of chloramphenicol base

Expiration date 12 months

RESTECLIN® 250 mg **Capsules**

RESTECLIN® 500 mg **Tablets**

Tetracycline Hydrochloride

Each Resteclin Capsule contains 250 mg crystalline tetracycline hydro

chloride and each Resteclin Tablet contains 500 mg crystalline tetracycline hydrochloride Although the chemical and physical properties as well as the antibacterial spectrum of tetracycline hydrochloride resemble those of oxytetracycline and chlortetracycline tetracycline hydrochloride offers the advantage of greater stability in plasma and on oral administration there are fewer gastrointestinal side effects In addition tetracycline hydrochloride rapidly achieves effective blood and tissue concentrations

Action Tetracycline hydrochloride provides proven therapeutic effectiveness against infections caused by a broad spectrum of micro organisms including both gram positive and gram negative bacteria spirochaetes certain rickettsiae viruses of the lymphogranuloma psittacosis trachoma group Eaton s agent and *Entamoeba histolytica* Following oral administration tetracycline hydrochloride is readily absorbed from the gastrointestinal tract with prompt establishment of fully effective blood concentrations The antibiotic is rapidly diffused into various body fluids including the cerebrospinal peritoneal and pleural fluids and the saliva It appears to be mainly excreted in urine although some portion of the ingested drug is excreted unchanged in the faeces

Advantages

Tetracycline in Resteclin
- is effective against a wide variety of organisms
- is readily absorbed from the gastrointestinal tract
- rapidly diffuses into body fluids

Indications Resteclin is indicated for many common infections including those of the respiratory gastrointestinal and genitourinary systems which are amenable to tetracycline therapy

Representative infections in which Resteclin may be used are

Pneumococcal Infections
lobar pneumonia

Streptococcal Infections
cellulitis
bronchopneumonia
follicular tonsillitis
meningitis
otitis media
pharyngitis
scarlet fever
septic sore throat
tonsillitis
tracheobronchitis
urinary tract infections

Staphylococcal Infections
abscesses
acute bronchitis
furunculosis
impetigo
laryngotracheitis
ophthalmic infections
osteomyelitis
otitis media
pharyngitis
septicaemia
sinusitis
urinary tract infections

Neisseria Infections
gonorrhoea
meningitis

Proteus Infections (due to tetracycline sensitive strains)

Escherichia coli Infections
abscesses
peritonitis
urinary tract infections

Shigella Infections
bacillary dysentery

Haemophilus Infections

Pertussis

Rickettsial Infections
epidemic typhus
Rocky Mountain spotted fever

Virus like Infections
lymphogranuloma
psittacosis
trachoma

Intestinal Amoebic Infections

Acute Brucellosis (in conjunction with streptomycin)

Resteclin is particula ly valuable in the treatment of mixed infections due to susceptible organisms and in conditions in which the causal agent has not been specifically identified for example pneumonia peritonitis chronic bronchiectasis sinusitis urinary tract infections postpartum endometritis puerperal mastitis and pancreatitis Resteclin is also recommended for mixed infections of the eye including conjunctivitis corneal infection peri orbital infection uveitis and some forms of blepharitis and for such pyo genic dermatologic conditions as secondarily infected atopic dermatitis sycosis and eczematous otitis externa Resteclin is also useful in pre operative and post operative prophylaxis

Dosage Dosage should be based on the tetracycline content The si ggested minimum adult dose is 250 mg four times daily Higher dosages such as 500 mg four times da ly may be required for severe infections or for those infections which do not respond to the smaller dose In gene al the paedia tric dose should supply 20 to 40 mg tetracycline per kg of body weight each day in divided doses depending on the type and severity of infection

Treatment of most common infections should generally continue for 24 to 48 hours after symptoms and fever subside However if used in the treat ment of streptococcal infections therapy should be continued for a full 10 days to guard against the risk of rheumatic fever or glomerulonephritis Even more prolonged therapy is necessary for subacute bacterial endo carditis and may be required in certain staphylococcal infections

Side Effects Tetracycline hydrochloride is generally well tolerated Undesirable side effects such as nausea vomiting and diarrhoea are significantly less frequent with tetracycline hydrochloride than with the two analogues oxy tetracycline and chlortetracycline

Precautions As with any antibiotic preparation prolonged use may result in overgrowth of nonsusceptible organisms including fungi (monilia) Con stant observation of the patient is essential Should superinfection occur the drug should be discontinued and/or appropriate therapy instituted

Tetracycline may form a stable calcium complex in any bone forming tissue with no serious harmful effects reported thus far in humans However use of tetracycline during tooth development (i e last trimester of pregnancy neonatal period and early childhood) may cause discolouration of the teeth (i e yellow grey brownish) This effect occurs mostly during long term use of the drug but it has also been observed in usual short treatment courses

Warning If renal impairment exists even usual oral or parenteral doses may lead to excessive systemic accumulation of the drug and possible liver toxicity Under such conditions lower than usual doses are indicated and if therapy is prolonged tetracycline serum level determinations may be advis- able

Presentation Resteclin 250 mg Capsules Strips of 10 capsules and boxes of 10 strips of 10 s Reclor 500 mg Tablets Strips of 4 tablets and boxes of 25 strips of 4 s

Expiration date 24 months

RESTECLIN® INTRAMUSCULAR — Sterile Powder

Tetracycline Hydrochloride for
Intramuscular Use with Lidocaine (Xylocaine§)

Resteclin Intramuscular is available in powder form in vials providing 100 mg crystalline tetracycline hydrochloride with 40 mg lidocaine hydrochloride buffered with 300 mg asco bic acid and 47 mg magnesium chloride Because lidocaine produces a more intensive and extensive anaesthetic effect the preparation contains lidocaine (Xylocaine) rather than procaine

Although the chemical and physical properties as well as the antibac terial spectrum resemble those of oxytetracycline and chlortetracycline tetracycline hydrochloride offers the advantage of greater stability in plasma and fewer gastrointestinal side effects In addition it rapidly achieves fully effective blood and tissue levels

Advantages

- broad spectrum activity against both gram positive and gram negative bacteria as well as *Entamoeba histolytica* and certain rickettsiae and viruses
- particularly valuable in the treatment of mixed infections
- prompt absorption from site of injection
- rapid antibacterial levels in blood cerebrospinal fluid and tissues
- prolonged antibacterial effect in urine
- greater stability in plasma than oxytetracycline or chlortetracycline
- minimal discomfort upon injection assured through the action of Xylo caine–the long acting local anaesthetic

Indications Resteclin Intramuscular is intended for those patients unable or unwilling to take oral therapy The parenteral form should be replaced by oral therapy as soon as the patient s condition permits

It exhibits antimicrobial activity against a wide variety of gram positive and gram negative bacteria rickettsiae *Entamoeba histolytica* and viruses of the lymphogranuloma psittacosis trachoma group

Representative infections in which Resteclin Intramuscular may be used are

Pneumococcal Infections
lobar pneumonia

Streptococcal Infections
cellulitis
bronchopneumonia
follicular tonsillitis
meningitis
otitis media
pharyngitis
scarlet fever
septic sore throat
tonsillitis
tracheobronchitis
urinary tract infections

Staphylococcal Infections
abscesses
acute bronchitis
furunculosis
impetigo
laryngotracheitis
ophthalmic infections
osteomyelitis
otitis media
pharyngitis
septicaemia
sinusitis
urinary tract infections

Neisseria Infections
gonorrhoea
meningitis

Proteus Infections (due to tetracycline sensitive strains)

Escherichia coli Infections
abscesses
peritonitis
urinary tract infections

Shigella Infections
bacillary dysentery

Haemophilus Infections

Pertussis

Rickettsial Infections
epidemic typhus
Rocky Mountain spotted fever

Virus like Infections
lymphogranuloma
psittacosis
trachoma

Intestinal Amoebic Infections

Acute Brucellosis (in conjunction with streptomycin)

Resteclin intramuscular is particulary valuable in the treatment of mixed infections and in conditions in which the causal agent has not been specifically identified for example pneumonia peritonitis chronic bronchiectasis sinusitis urinary tract infections postpartum endometritis peurperal mastitis and pancreatitis The preparation is also recommended for mixed infections of the eye including conjunctivitis corneal infections periorbital infection uveitis and some forms of blepharitis and for such pyogenic dermatologic conditions as secondarily infected atopic dermatitis sycosis and eczematous otitis externa Resteclin Intramuscular is also useful in pre and post operative prophylaxis

Contraindications This drug is contraindicated in individuals with a history of tetracycline sensitivity

Warning If renal impairment exists even usual oral or parenteral doses may lead to excessive systemic accumulation of the drug and possible liver toxicity Under such conditions lower than usual doses are indicated and if therapy is prolonged tetracycline serum level determinations may be advisable

Certain hypersensitive individuals may develop a photodynamic reaction precipitated by a direct exposure to natural or artificial sunlight during the use of this drug This reaction is usually of the photoallergic type which may also be produced by other tetracycline derivatives Individuals with a history of photosensitivity reactions should be instructed to avoid direct exposure to natural or artificial sunlight while under treatment with this or other tetracycline drugs and treatment should be discontinued at first evidence of skin discomfort

Note Photosensitization reactions have occurred most frequently with demethylchlortetracycline less with chlortetracycline and very rarely with oxytetracycline and tetracycline hydrochloride

Precautions Therapy should be given under the constant supervision of a physician The use of any broad spectrum antibiotic may result in overgrowth of non susceptible organisms particularly monilia If new infections appear during therapy appropriate measures should be taken Tetracycline may form a stable calcium complex in any bone forming tissue with no serious harmful effects reported thus far in humans However use of tetracycline during tooth development (i e last trimester of pregnancy neonatal period and early childhood) may cause discolouration of the teeth (i e yellow grey brownish) This effect occurs mostly during long term use of the drug but it has also been observed in usual short treatment courses

Increased intracranial pressure with bulging fontanels has been observed in infants taking therapeutic doses of tetracycline Occurrence has been rare and all signs and symptoms have disappeared rapidly upon cessation of treatment In the treatment of gonorrhoea patients with a suspected lesion of syphilis should have darkfield examinations before receiving tetracycline and monthly serologic tests for a min mum of three months

The use of tetracycline in staphylococcal infections does not preclude the need for indicated surgical procedures

Administration The preparation should be administered by deep intramuscular injection following aspiration to be sure the needle is not in a vein The preferred site is the upper outer quadrant of the buttock Deposition in the subcutaneous tissues should be avoided accidental injection into these tissues may cause pain and induration which can be alleviated by applying an ice bag

Directions for Reconstitution Add 2 ml Sterile Water for Injection in the following manner Loosen the powder hold the vial horizontally and rotate it while *slowly* directing the stream of diluent against the wall of the vial shake the vial vigorously after the diluent has been added

Dosage Adults Intramuscular administration of 200 to 300 mg per day given in divided doses of 100 mg every 8 to 12 hours is generally adequate for the treatment of susceptible infections of mild or moderate severity In more severe infections or in those patients not responding to the above dosage schedule 100 mg every 4 or 6 hours may be given

Infants and Children Dosage for infants and children should be proportionately less than the adult dose depending on the age weight and severity of the condition being treated

Therapy should be continued one or two days after signs and symptoms of the disease being treated have subsided If a tetracycline preparation is used to treat haemolytic streptococcal infections therapy should be continued for at least 10 days to guard against the risk of rheumatic fever or glomerulonephritis Even more prolonged therapy is necessary for subacute bacterial endocarditis and for certain staphylococcal infections

Presentation Resteclin Intramuscular vials of 100 mg boxes of 5 vials

Expiration date 24 months at room temperature After reconstitution may be stored at room temperature but should be used within 24 hours

RESTECLIN® INTRAVENOUS — Sterile Powder

Tetracycline Hydrochloride Crystalline Buffered with Ascorbic Acid (Vitamin C) for Intravenous Use

Resteclin Intravenous is Tetracycline Hydrochloride for Injection Although the chemical and physical properties as well as the antibacterial spectrum resemble those of oxytetracycline and chlortetracycline tetracycline hydrochloride offers the advantage of greater stability in plasma and rapid achievement of effective blood and tissue concentrations

Resteclin Intravenous is available in powder form in vials of 250 mg and 500 mg with vitamin C as a buffer

Rationale for Use Resteclin Intravenous is intended for those unable or unwilling to take oral Resteclin therapy The parenteral form of Resteclin should be replaced by oral therapy as soon as the patient s condition permits

Indications Tetracycline hydrochloride has exhibited antimicrobial activity against a wide variety of gram positive and gram negative bacteria rickettsiae *Entamoeba histolytica* and viruses of the lymphogranuloma-psittacosis-trachoma group Resteclin Intravenous is indicated in the treatment of infections caused by susceptible organisms

Representative infections in which Resteclin Intravenous may be used are

Pneumococcal Infections
lobar pneumonia

Streptococcal Infections
cellulitis
bronchopneumonia
follicular tonsillitis
meningitis
otitis media
pharyngitis
scarlet fever
septic sore throat
tonsillitis
tracheobronchitis
urinary tract infections

Staphylococcal Infections
abscesses
acute bronchitis
furunculosis
impetigo
laryngotracheitis
ophthalmic infections
osteomyelitis
otitis media
pharyngitis
septicaemia
sinusitis
tracheobronchitis
urinary tract infections

Neisseria Infections
gonorrhoea
meningitis

Proteus Infections (due to tetracycline sensitive strains)

Escherichia coli Infections
abscesses
peritonitis
urinary tract infections

Shigella Infections
bacillary dysentery

Haemophilus Infections

Pertussis

Rickettsial Infections
epidemic typhus
Rocky Mountain spotted fever

Virus like Infections
lymphogranuloma
psittacosis
trachoma

Intestinal Amoebic Infections

Acute Brucellosis (in conjunction with streptomycin)

Resteclin Intravenous is particularly valuable in the treatment of mixed infections and in conditions in which the causal agent has not been specifically identified for example pneumonia peritonitis chronic bronchiectasis sinusitis urinary tract infections postpartum endometritis puerperal mastitis and pancreatitis Resteclin Intravenous is also recommended for mixed infections of the eye including conjunctivitis corneal infections periorbital infection uveitis and some forms of blepharitis and for such pyogenic dermatologic conditions as secondarily infected atopic dermatitis sycosis and eczematous otitis externa Resteclin Intravenous is also useful in pre and post operative prophylaxis

Administration Administration by intravenous drip is the method of choice although direct intravenous injection may be made if necessary

For Intravenous Drip Therapy Resteclin Intravenous should be reconstituted with Sterile Water for Injection by adding 5 ml or 10 ml to the 250 mg vial and 10 ml to the 500 mg vial The preferable concentration for intravenous drip is 0 1% or less (1 mg/ml) which may be attained by further dilution of the solution with one of the standard intravenous solutions such as

5% Dextrose Injection
Dextrose and Sodium Chloride Injection (Dextrose 5%)
Sodium Chloride Injection
Lactated Ringer s Injection

The usual rate of injection by intravenous drip is 5 to 10 ml per minute

For Direct Intravenous Therapy Each 100 mg Resteclin Intravenous should be dissolved in 10 ml Sterile Water for Injection to make a 1% solution The 1% solution may be administered directly by vein allowing about 5 minutes for each 10 ml (100 mg) of the solution

Dosage Adults The *average* adult dose for Resteclin Intravenous is 500 mg every 12 hours The *maximum* adult dose is 500 mg intravenously every 6 hours Duration of therapy should depend on the nature and severity of the infection Therapy with Resteclin Intravenous should be continued 2 or 3 days after signs and symptoms of the disease being treated have subsided Parenteral therapy with Resteclin Intravenous should be replaced by oral therapy as soon as the patient s condition permits

If tetracycline is used to treat haemolytic streptococcal infections therapy should be continued for at least 10 days to guard against the risk of rheumatic fever or glomerulonephritis Even more prolonged therapy is necessary for subacute bacterial endocarditis and for certain staphylococcal infections

Precautions The usual precautions for intravenous therapy should be observed As with other intravenously administered drugs local inflammatory reactions at the injection site or thrombophlebitis may occur in some patients Resteclin therapy should be given under the constant supervision of a physician

The use of any broad spectrum antibiotic may result in overgrowth of non susceptible organisms particularly monilia If new infections appear

during therapy appropriate measures should be taken Intestinal moniliasis which may occur following oral administration of broad spectrum antibiotics can be prevented or treated with Mycostatin (Nystatin) or Fungizone (Amphotericin B)

Presentation Resteclin Intravenous vials of 250 mg and 500 mg

Expiration date 24 months at room temperature After reconstitution may be stored at room temperature but should be used within 24 hours

RESTECLIN® OINTMENT

Ointment

Tetracycline Hydrochloride

Resteclin is Tetracycline Hydrochloride It is an antibiotic of known structure obtained in the crystalline state Resteclin Ointment is indicated for the topical treatment and prophylaxis of local infections due to a large variety of gram positive and gram negative micro organisms Resteclin Ointment is formulated in a new emollient and protective ointment base Plastobase® (Plasticized Hydrocarbon Gel) Plastobase is odourless colourless and non-irritating It is easy to apply Resteclin Ointment prepared with Plastobase does not stain the skin or clothing and the patient readily accepts it Each gramme of Resteclin Ointment provides 30 mg tetracycline hydrochloride

Indications Resteclin Ointment is indicated in local infections sensitive to the antibiotic It has been found effective in infections due to some gram positive and gram negative organisms as well as in various mixed bacterial infections Resteclin Ointment can be used specifically in skin infections including pyogenic infections pyodermatitis dermatitis pustulosa minor infected wounds or abrasions and secondary infections accompanying minor burns The ointment is also indicated in the prevention of local secondary infections of minor wounds and surgical interventions

Administration Resteclin Ointment is especially prepared for topical therapy Resteclin Ointment should be applied to the skin two or three times a day until recovery is complete The length of treatment varies according to the nature and severity of the infection to be treated When crusts are present these must be removed by wet compresses or water and soap before Resteclin Ointment is applied

Note When treating infections that can spread systemically the topical administration of Resteclin should be supplemented by oral therapy

Tolerance Resteclin Ointment is well tolerated In some individuals allergic reactions can occur If so administration of the ointment should be suspended and appropriate therapeutic measures adopted

Presentation Tubes of 15 g

Expiration date 36 months at room temperature

RESTECLIN® OPHTHALMIC OINTMENT — Ophthalmic Ointment

Tetracycline Hydrochloride

Resteclin is Tetracycline Hydrochloride a crystalline antibiotic of known structure Resteclin Ophthalmic Ointment is intended for topical application in the treatment of infections of the eye caused by a variety of gram positive and gram negative organisms Resteclin Ophthalmic Ointment is formulated in a new emollient protective and non irritating ointment base Plastobase® (Plasticized Hydrocarbon Gel) Each gramme of Resteclin Ophthalmic Ointment provides 10 mg crystalline tetracycline hydrochloride

Indications Resteclin Ophthalmic Ointment is indicated in the treatment of ocular infections caused by staphylococci pneumococci Haemophilus influenzae Morax Axenfeld diplobacillus Friedlaender bacillus Streptococci Aerobacter aerogenes Proteus vulgaris Proteus morganii Escherichia coli Alcaligenes faecalis Pseudomonas pyocyanea and in the treatment of trachoma

Viral or viral like ocular infections responding to Resteclin Ophthalmic Ointment include follicular conjunctivitis inclusion conjunctivitis and dendritic keratitis

Administration and Dosage Apply to affected eye every 2 hours or oftener as the condition and response indicate Severe infections may require treatment for several days In certain instances oral adjuvant tetracycline may be required Mild infections may respond in as little as 48 hours

Precaution Overgrowth of non susceptible organisms may occur following use of antibiotics Close observation with appropriate measures when necessary is required for all patients

Tolerance Resteclin Ophthalmic Ointment is well tolerated Allergic reactions may occur in certain individuals If such reactions are encountered use of the ointment should be discontinued and appropriate therapy instituted

Presentation Tubes 3 5 g with ophthalmic tip

Expiration date 36 months at room temperature

RUBRAFERATE® — Capsules

Iron Vitamin C Vitamin B_{12} and Folic Acid

Rubraferate is Vitamin B_1 Folic Acid Iron and Vitamin C (Ascorbic Acid) for oral use

Each Rubraferate Capsule provides

Vitamin B_{12} (as B_{12} Activity Concentrate Oral Powder)	4 17 mcg
Ferrous Sulphate Exsiccated (supplying 38 mg Iron)	0 13 g
Vitamin C (Ascorbic Acid)	50 mg
Folic Acid	0 28 mg

Indications Rubraferate may be used in the treatment of many of the common macrocytic anaemias except pernicious anaemia including nutritional macrocytic anaemia tropical sprue and nontropical sprue and the megaloblastic anaemias of infancy Rubraferate is particularly indicated in the treatment of anaemias caused primarily by iron deficiency complicated by deficiencies of other nutrients Rubraferate may also be useful in anaemias associated with dietary inadequacy commonly characterized by malaise and chronic fatigue

Note When the diagnosis of Addisonian pernicious anaemia has been confirmed treatement with parenterally administered vitamin B_{12} should be instituted

Dosage The recommended therapeutic dose is 2 Rubraferate Capsules three times daily or as prescribed by the physician A smaller daily dose may be used for maintenance therapy after blood values have reached normal levels When on maintenance therapy the patient should be watched carefully and a higher daily dose substituted if there is a clinical remission or if the blood values decline

When Rubraferate is given as a dietary supplement the suggested dose is 1 capsule daily or as directed by the physician

Presentation Bottles of 25 and 100 capsules

Note Keep bottle tightly closed Avoid exposure to extreme heat and sun light

Expiration date 24 months

RUBRAGRAN® HP — Capsules

High Potency Haematinic

Rubragran HP is a High Potency Haematinic combination for oral administration

Each Rubragran HP Capsule contains

Ferrous Fumarate	300 mg
Vitamin C	100 mg
Pyridoxine	10 mg
Folic Acid	2 5 mg
Vitamin B_{12}	50 mcg

Action Nutritional deficiencies seldom occur in a single essential factor and the altered physiology induced by deficiency of one essential nutrient may increase the body s need for other nutrients It is therefore desirable to provide five nutrients fundamental in normal red blood cell development Rubragran HP supplies all five factors in adequate amount for normal haemopoiesis

Rubragran HP supplies

Iron Essential constituent of haemoglobin molecule fundamental in preventing and correcting hypochromia and microcytosis Ferrous fumarate is regarded as an easily tolerated well absorbed and adequately utilizable form of oral iron

Vitamin C Necessary for haemopoiesis aids the absorption and utilization of iron and plays a singnificant role in the maturation of red blood cells Vitamin C deficiency can cause a normocytic or macrocytic anaemia which will not respond to liver extract or iron but will respond to Vitamin C Evidence exists to show that Vitamin C has a sparing action on available folic acid

Pyridoxine Although anaemia is not usually a feature of true or conditioned pyridoxine deficiency occasionally megaloblastic erythropoiesis occurs Hypochromic anaemia refractory to treatment with iron given orally or parenterally may respond well to the oral administration of pyridoxine hydrochloride Pyridoxine is also useful for anaemia due to certain anti tuberculous drugs The mechanism of B_6 responsive anaemia has not been satisfactorily elucidated

Vitamin B_{12} and Folic Acid Both are necessary to prevent or reverse megaloblastic arrest of bone marrow and the resulting macrocytic hyper chromic peripheral blood Neither Vitamin B_{12} nor folic acid appears to be effective in the complete absence of the other Clinical evidence intimately associates both Vitamin B_{12} and folic acid with the true erythrocyte matu ration factor in at least some macrocytic anaemias

Indications Rubragran HP is indicated in the treatment of many of the common anaemias whether they are primarily of macrocytic or microcytic origin including nutritional macrocytic anaemia hypochromic microcytic anaemia macrocytic anaemia of pregnancy and tropical and non tropical sprue Rubragran HP is also particularly useful in the t eatment of anaemias caused primarily by iron deficiency Rubragran HP may be useful in anaemias associated with dietary inadequacy commonly characterized by malaise and chronic fatigue It can also be used in anaemia associated with antituberculous therapy

Vitamin B_{12} should be given parenterally in the treatment of pernicious anaemia and hence Rubragran HP is not indicated in the treatment of Addisonian pernicious anaemia

Precaution Folic acid corrects the blood picture of pernicious anaemia but does not ameliorate the attendant neurologic involvement Therefore Rubragran-HP *is not indicated in pernicious anaemia*

Dosage The suggested therapeutic dose is one capsule of Rubragran HP two times daily

Presentation Rubragran HP is supplied in bottles of 14 capsules

Expiration date 24 months

RUBRAMIN® — Parenteral Solution

Cyanocobalamin (Vitamin B_{12}) Injection

Rubramin is Cyanocobalamin (Vitamin B_{12}) Injection available for intra muscular use as a sterile clear aqueous solution with a characteristic pink colour

Indications The efficacy of Rubramin in alleviating neurologic manifestations of

pernicious anaemia suggests the possible usefulness of the vitamin in relieving the pain of sensory neuropathies Massive doses of vitamin B_{12} may produce relief of the most severe aspects of the pain of trigeminal neuralgia (tic douloureux) and eventually complete or partial relief of secondary burning paraesthesia

Significant improvement has been reported in about 80% of approximately 150 patients with trigeminal neuralgia when given vitamin B_{12} and with slight or no improvement in the remaining 20% Of the patients responding to treatment relief of pain was prompt and virtually complete in about 60% and partial but satisfactory in the remainder With the latter group pain gradually disappeared or remained as local tenderness as treatment continued Remission of pain has persisted for 6 months to more than a year in about 40% of the patients responding to the initial course of vitamin B_{12} Additional courses at intervals of 1 to 8 months have produced satisfactory pain relief in the remainder A few patients however require weekly or biweekly doses of vitamin B_{12} for maintenance of pain relief

There are clinical reports which indicate that high doses of vitamin B_{12} may be of benefit in relieving pain associated with diabetic neuritis alcoholic neuritis and other neuritides where pain is a major component

Dosage In trigeminal neuralgia the suggested daily dose of Rubramin Solution ranges from 250 to 1 000 mcg intramuscularly subcutaneously or intravenoulsy Treatment is continued until relief is obtained Fields and Hoff† recommended a daily injection of 1 000 mcg for 10 days although their earlier patients responded favourably to a dose of 1 000 mcg given 2 or 3 times weekly for 4 to 8 weeks

Following the initial course of treatment additional Rubramin therapy is suggested if and when paroxysmal pain recurs The duration and frequency with which subsequent courses of Rubramin are given depend on the individual patient response

No toxic or cumulative effects have been reported following massive doses of vitamin B_{12}

Presentation Rubramin Solution is available in the following potencies

5 ml vials of 100 mcg vitamin B_{12} (Cyanocobalamin) per ml
5 ml vials of 500 mcg vitamin B_{12} (Cyanocobalamin) per ml
5 ml vials of 1 000 mcg vitamin B_{12} (Cyanocobalamin) per ml

Expiration date 36 months

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† Field W S and Hoff H E Neurology 2 131 (1952)

RUBRAMIN® H — Parenteral Solution

Hydroxocobalamin (Vitamin B_{12}b) Injection

Rubramin H is Hydroxocobalamin (Vitamin B_{12}b) Injection available for intramuscular use as a sterile clear aqueous solution with a characteristic deep red colour It differs from cyanocobalamin preparations by the replacement of the cyano group with the hydroxyl group

Action Rubramin H induces remission of pernicious anaemia like cyanocobalamin but it is retained in the body in greater amounts and for longer periods than cyanocobalamin Increased retention of Rubramin H (Hydroxocobalamin) is reflected in a corresponding decrease in urinary excretion The blood level obtained with Rubramin H after 5 hours is 4 1 times higher than that of Rubramin after 24 hours it is 12 8 times higher and after 4 weeks it is 5 2 times higher when both are administered intramuscularly in a dose of 1 000 mcg

Indications Rubramin H is indicated for pernicious anaemia with or without neurologic complications The preparation is also of value in the treatment of other macrocytic megaloblastic anaemias where aetiology suggests malabsorption of vitamin B_{12} such as anaemia following gastrectomy or associated with gastric carcinoma macrocytic anaemia of pregnancy and puerperium and the megaloblastic anaemias associated with such gastro intestinal disorders as tropical and non tropical sprue (In certain macrocytic anaemias vitamin B_1 may fail to produce a satisfactory response folic acid being indicated alone or in combination with Rubramin H)

Higher doses of Rubramin H may be of benefit in trigeminal neuralgia diabetic neuritis alcoholic neuritis nerpes zoster and other neuropathies associated with diabetes malnutrition and alcoholism where pain is a major component

Hydroxocobalamin is also indicated in nutritional polyneuropathy vitamin responsive genetically determined disease like methyl melanic aciduria and deficiency amblyopia (nutritional optic neuropathy tobacco alcohol amblyopia)

Advantages Rubramin H is capable in providing consistently higher more prolonged blood serum levels This fact is particularly important in the initial therapy of severe pernicious anaemia and other conditions involving serious depletion of vitamin B_{12} in which prompt replacement of body stores of vitamin is essential

Adequate parenteral doses of Rubramin H prevent or alleviate the neurological complications of pernicious anaemia particularly subacute combined system disease However long standing neurologic involvement may have progressed to the stage where damage is largely irreversible despite intensive vitamin B_{12} therapy

Dosage The dose requirements for vitamin B_{12} vary with the individual patient and with the condition being treated For uncomplicated pernicious anaemia the suggested initial dose of Rubramin H is 100 mcg/day for a week The frequency of administration may then be decreased the goal being to give a total of 1000 mcg during the first 6 weeks The patient must then be placed on 100 mcg vitamin B_1 for the rest of the patient s life

In sprue 15 to 30 mcg intramuscularly once or twice per week is generally sufficient to induce remission If needed oral therapy may then be instituted

In nutritional macrocytic anaemia a single initial intramuscular dose of 15 mcg usually produces a favourable response Oral therapy may be instituted or the dose may be repeated every two weeks to prevent relapse Concomitant therapy with folic acid may be required For the treatment of

neuritis and other neuropathies high dosage of 500 to 1 000 mcg may be given at weekly intervals

Side Effects Very few reactions have been observed following parenteral administration No toxic or cumulative effects have been reported following massive doses of vitamin B_{12} Evidence indicates that patients unable to tolerate liver extracts may receive vitamin B without untoward effect

Presentation 500 mcg/ml and 1 000 mcg/ml vials of 5 ml

Expiration date 36 months

RUBRAPLEX®

Elixir

Iron B Complex and B_1 Vitamins Elixir

Rubraplex is a haematinic elixir containing Iron B Complex and B Vitamins It supplies two important blood building factors as well as vitamins of the B Complex group Rubraplex is a pleasant tasting fruit flavoured elixir which may be taken directly from the spoon or mixed with a small amount of water fruit juice or milk Its excellent palatability makes Rubraplex particularly useful in patients who object to or are unable to take capsules or tablets

Each 5 ml (approximately 1 teaspoonful) of Rubraplex provides

Elemental Iron (as Ferric Ammonium Citrate and Colloidal Iron)	38 0 mg
Vitamin B_{12} (Cyanocobalamin)	4 0 mcg
Vitamin B_1 (Thiamine Mononitrate)	1 0 mg
Vitamin B (Riboflavine 5 Phosphate Sodium)	1 0 mg
Vitamin B_6 (Pyridoxine Hydrochloride)	0 5 mg
d Panthenol	1 5 mg
Niacinamide	5 0 mg
Alcohol content 12% by volume	

Indications Rubraplex is indicated in the treatment of anaemias due to nutritional deficiency By virtue of its iron content Rubraplex is particularly useful in the management of iron deficiency anaemias Specifically Rubraplex is useful in the treatment of nutritional macrocytic anaemia and in the iron deficiency anaemias of infancy childhood and puberty as well as in anaemias of women from menarche to menopause The preparation also of value in the treatment of anaemias attending convalescence The B Complex vitamin content of Rubraplex makes the preparation suitable for the treatment of deficiencies of these vitamins

Rubraplex is not intended for the treatment of pernicious anaemia

Advantages

- replenishes B Complex and B_{12} vitamin reserves essential for all body tissues including blood
- regenerates blood by supplying elemental iron
- restores physical well being of patients

Dosage Two teaspoonfuls (10 ml) three times daily

Administration Rubraplex is a pleasant tasting preparation and may be given directly from the spoon However if preferred the preparation may be mixed with a small amount of water fruit juice or milk

Presentation Rubraplex is available in bottles of 120 ml 240 ml and 480 ml

Note Bottles of Rubraplex should be kept tightly closed and stored in a cool place Exposure to sunligh should be avoided

Expiration date 18 months

RUBRAPLEX® INJECTION — Parenteral Solution

Vitamin B Complex Injection

Rubraplex Injection Vitamin B Complex Injection for intramuscular use contains six important physiologically and therapeutically useful members of the B Complex vitamins Rubraplex Injection formula is based on he recommendations of the National Formulary of India

Each ml Rubraplex Injection supplies

Vitamin B_{12} (Cyanocobalamin)	10 mcg
Vitamin B_1 (Thiamine Hydrochloride)	15 mg
Vitamin B (Riboflavine)	2 mg
Niacinamide	100 mg
Vitamin B_6 (Pyridoxine Hydrochloride)	5 mg
Panthenol	5 mg

Indications Rubraplex Injection contains all the major factors of vitamin B Com plex in adequate amounts it is useful for the vitamin B Complex deficiency states met with in clinical practice Deficiency of a single factor of B Complex is relatively rare without a latent deficiency of other B Complex factors also Hence Rubraplex Injection is indicated for the treatment of vitamin B Complex deficiency symptoms These symptoms can be mani fested as glossitis stomatitis ulcers of the mucous membranes of mouth cheilosis conjunctivitis photophobia epiphora scleral injection vomiting anorexia diarrhoea neuritis paraesthesias tenderness of calf muscles weakness fatigue vague neuritic pain pellagrous dermatitis burning foot syndrome etc It is also useful for debility during convalescence vitam in B Complex deficiency due to broad spectrum antibiotic therapy chronic debi litating diseases and diabetes mellitus

Administration of Rubraplex Injection provides for the increased vitamin requirements accompany ng alcoholism thyrotoxicosis serious illness or tissue damage caused by injury burns exessive radiation or surgery Post operatively Rubraplex Injection therapy is recommended in the presence of anorexia or vomiting particularly for patients receiving infusions of saline or glucose as such infusions may cause rapid depletion of water soluble vitamins by increasing their rate of urinary excretion Moreover many of the B Complex vitamins form enzymes essential for the oxidation of glucose and infusions of glucose solutions may deplete tissue stores of B vitamins

To compensate for this loss adequate amounts of these vitamins should be administered along with the infusion solutions Since B vitamins are also concerned with protein and amino acid metabolism liberal quantities of the vitamin B Complex should be given to patients receiving amino acid or protein preparations parenterally

Rubraplex Injection is specially indicated in severe B Complex deficiencies particularly in patients who cannot tolerate oral medication or in whom there is evidence of poor gastrointestinal absorption

Dosage One ml intramuscularly once or twice a day as may be decided by the physician

Presentation Vials of 10 ml

Expiration date 12 months Store in a cold place below 15 C

RUBRATON®

Elixir

Iron B_{12} Folic Acid Elixir

Rubraton combines three fundamental blood building factors in an exceptionally pleasant tasting elixir

Each teaspoonful (5 ml) of Rubraton contains

Ferric Ammonium Citrate (providing Iron 38 mg)	0 177 g
Vitamin B_{12}	4 17 mcg
Folic Acid	0 28 mg
Alcohol content 12% by volume	

Indications Rubraton may be used for therapy in nutritional macrocytic anaemia the megaloblastic anaemia of infancy and in sprue When iron deficiency is complicated by deficiencies of other nutrients Rubraton is also indicated It may be especially useful in anaemias which are difficult to classify and treat

Therefore Rubraton may be useful in the anaemias attending convalescence the microcytic and normocytic anaemias of pregnancy the anaemias of chronic bleeding and the iron deficiency anaemias of infancy childhood and puberty In addition Rubraton may be used experimentally for the promotion of growth in children It is also useful in patients who object to capsules or tablets *Rubraton is not intended for the treatment of pernicious anaemia*

Advantages Because of its contents of folic acid and vitamin B_{12} Rubraton offers a pleasant oral method for treating those anaemias other than pernicious anaemia characterized by megaloblastic arrest of the bone marrow In addition its iron content makes Rubraton specific in iron deficiency Because it is a liquid Rubraton offers better absorption of its constituents

Dosage In treating any anaemia it is probably best to administer an excess of haematogenic essentials Hence in the average case therapy should be started with 2 teaspoonfuls of Rubraton t i d Each dose should be taken in

half a glass of water milk or fruit juice When indicated by clinical and haematologic response the dose may be lowered to 1 teaspoonful t i d When on maintenance therapy the patient should be carefully watched and a higher dose substituted if there appears to be a clinical regression or if the blood values decline

Presentation Bottles of 120 ml 240 ml and 480 ml

Note Keep tightly closed Avoid exposure to sunlight

Expiration date 18 months

RUBRATON® PEDIATRIC — Elixir

Iron B_1 Folic Acid Elixir

Rubraton Pediatric is a good tasting liquid supplying therapeutic amounts of three essential blood building factors

Each teaspoonful (5 ml) Rubraton Pediatric contains

Ferric Ammonium Citrate (providing Iron 38 mg)	0 177 g
Vitamin B_{12}	4 17 mcg
Folic Acid	0 28 mg
Alcohol content 5% by volume	

Indications Rubraton Pediatric combats anaemia (except pernicious anaemia) due to nutritional deficiencies in children Rubraton supplies three important blood building factors in therapeutically effective amounts in a formulation acceptable in taste to the most exacting child

Rubraton Pediatric is indicated for the treatment of anaemia (except pernicious anaemia) due to nutritional deficiencies in infants and children Rubraton Pediatric has been used to promote growth in children

Administration Rubraton Pediatric may be taken directly from a spoon or mixed with a small amount of water fruit juice or milk

Dosage Children under 2 years – 1 teaspoonful three times daily
Children 2 years and over – 2 teaspoonfuls three times daily
Maintenance therapy – 1 teaspoonful three times daily

Presentation Bottles of 60 ml

Note Keep tightly closed Avoid exposure to sunlight

Expiration date 18 months

SIQUIL® — Tablets Parenteral Solution

Triflupromazine Hydrochloride

Siquil Triflupromazine Hydrochloride is a highly potent phenothiazine derivative chemically designated as 10 (3-dimethylaminopropyl) 2-(trifluoromethyl) phenothiazine hydrochloride Siquil is available for oral and

parenteral administration Oral and parenteral Siquil are indicated in the control of nausea and vomiting as pre and post operative sedative agents in obstetrics and in the management of anxiety and tension states Oral and parenteral Siquil are also of value in the treatments of psychiatric disorders and of alcoholism For oral use Siquil is supplied as press coated tablets For parenteral administration Siquil is available in ampoules and multiple dose vials

Action Modification of the phenothiazine structure as achieved in Siquil has resulted in a potentiation of beneficial pharmacologic properties with a concomitant reduction and attenuation of unwanted physiologic effects Clinical appraisal has demonstrated that Siquil is at least twice as potent as chlorpromazine in controlling psychotic manifestations in animal studies Siquil exhibited a three to five fold increase in activity when compared with chlorpromazine In clinical trials Siquil has shown a unique ability to control psychomotor agitation without producing marked sedation These studies have revealed that sedation is not a necessary requisite in achieving pharmacologic benefits on psychotic symptoms such as agitation delusions hallucinations or delirium Thus trifluprornazine does not put the patient into a state of lethargy and apathy but rather allows the patient to be approached for training purposes and eventual rehabilitation Investigation of the clinical effectiveness of trifluprornazine as an antiemetic agent has shown the compound to be at least 5 times as potent as chlorpromazine in arresting nausea and vomiting

The site and mode of action of phenothiazine derivatives including trifluprornazine are largely a matter of speculation Experimental and clinical studies suggest that these compounds act on the hypothalamus These drugs are believed to depress various components of the mesodience phalic activating system which is involved in the control of basal metabolism and body temperature wakefulness vasomotor tone emesis and hormonal balance In addition the drugs exert a peripheral autonomic effect Like other phenothiazines trifluprornazine prolongs and intensifies the action of many central nervous system depressants such as barbiturates narcotics and anaesthetics

Advantages

- increased potency without increased toxicity
- may be administered orally intramuscularly or intravenously – well tolerated by all routes of administration
- useful in children as well as adults
- tranquillizes the patient without marked sedation
- usually has no significant effect on blood pressure after oral administration
- relieves anxiety and tension with a minimum of unpleasant side effects
- is a superior anti emetic agent preventing or correcting emesis resulting from any of numerous causes
- provides extraordinary benefits when used prior to general anaesthesia since trifluprornazine does not interfere with respiration
- used adjunctively in the immediate post anaesthetic period prevents or corrects emergence delirium
- as an adjunct to obstetrical analgesia potentiates the analgesic action of narcotics and sedatives and increases the tolerance to pain

- allays the distress of the post alcoholic state
- favourably modifies aggressive and hostile psychotic behaviour diminishes or dispels hallucinations and delirium and restores or increases the accessibility of the patient to other forms of therapy
- is a versatile phenothiazine derivative

Indications

NAUSEA AND VOMITING

Parenteral and oral Siquil are indicated in the control and prevention of nausea and vomiting associated with a variety of clinical disorders Specifically Siquil is useful in the control and prevention of nausea and vomiting associated with such clinical disorders as certain diseases acute infections certain neurological procedures such as encepnalography and ventriculography certain drugs radiation therapy and nitrogen mustard therapy The drug is of particular value for prophylaxis and therapy of nausea and vomiting of early pregnancy up to and including the 12th week as well as hyperemesis gravidarum and for the control of post operative emesis

OBSTETRICS

As an adjunct to narcotics and general anaesthetics during the first and second stages of labour the administration of Siquil has a three fold purpose It provides a calming and sedative effect it intensifies the action of narcotics and anaesthetics so that dosage of these drugs can be greatly reduced and it appreciably lowers the incidence of vomiting No apparent effects on the new born have been encountered following the use of triflupromazine

PRE- AND POST OPERATIVE TRANQUILLIZATION

Parenteral Siquil has been used with great success preoperatively particularly in combination with local anaesthesia It is also well suited for use prior to general anaesthesia since t does not interfere with respiration Moreover its potentiating effect on general anaesthetics allows a reduction in the dosage of these agents Although triflupromazine has been used prior to spinal anaesthesia without any untoward effects it is generally not recommended when spinal anaesthesia is contemplated

ALCOHOLISM

T ifluprornazine has been of great value in the alleviation of restlessness anxiety insomnia and other emotional side effects commonly accompanying the withdrawal of alcohol

ANXIETY AND TENSION

The ataractic effects of trifluprornazine are beneficial in the treatment of functional complaints arising from anxiety and tension and in the allevia tion of apprehension associated with such conditions as neurodermatitis arthritis and cardiovascular disease

MENTAL DISORDERS

Because of its highly potent behaviour modifying properties the drug is useful in the management of psychomotor agitation associated with various acute and chronic psychoses including schizophrenia mania depression delirium senile psychoses and psychoses due to organic brain

disease or mental deficiency Trifluprομazine may be used with appropriate caution in mental disorders associated with epilepsy

BEHAVIOURAL PROBLEMS IN CHILDREN

Siquil is indicated in the management of primary behavioural problems in children

Contraindications Phenothiazine derivatives are contraindicated in patients with suspected or established subcortical brain damage with or without hypothalamic damage since a hyperthermic reaction with temperatures in excess of 104 F has been reported to occur sometimes as late as 14 to 16 hours after drug administration Total body ice packing is recommended for such a reaction antipyretics may also be useful

Because trifluprομazine may induce drowsiness in some patients driving a motor vehicle or operating machinery while under trifluprομazine therapy is not recommended

Phenothiazine compounds should not be used in patients receiving large doses of hypnotics and should be used with caution in patients with a history of convulsive disorders since grand mal convulsions have been known to occur

Patients with special medical disorders such as mitral insufficiency or pheochromocytoma and patients who have exhibited idiosyncrasy to other centrally acting drugs may experience severe reactions to phenothiazine compounds

Adverse Reactions and Precautions The most frequently reported side effects associated with phenothiazine administration are reversible extrapyramidal symptoms including Parkinsonism dystonia dyskinesia akathisia oculogyric crises opisthotonos and hyperreflexia Although these reactions may be alarming all are reversible and disappear if dosage is lowered or therapy is temporarily discontinued More rapid reversal may be achieved by administration of anti Parkinsonian drugs or intravenous Caffeine and Sodium Benzoate Injection

Skin disorders such as itching erythema urticaria and even exfoliative dermatitis have occurred with phenothiazine compounds Photosensitivity manifested as an erythematous macular eruption in sun exposed areas has been reported

The possibility of anaphylactoid reactions occurring in some patients should be borne in mind

Oral administration of trifluprομazine has produced dissociation of the cerebrospinal fluid protein pattern A severe hypertensive reaction following 25 mg of the drug was reported in one patient Reactivation of psychotic processes or induction of a catatonic like state may occur

Drowsiness or lethargy if they appear may necessitate a reduction in dosage Peripheral oedema endocrine disturbances such as abnormal lactation and autonomic reactions including nausea dry mouth headache and constipation may occur Autonomic effects can usually be controlled by reducing or temporarily discontinuing dosage

Hypotension appears to be a particular problem in patients with pheochromocytoma or mitral insufficiency If severe hypotension should occur supportive measures including the use of intravenous vasopressor drugs should be instituted immediately Levarterenol Bitartrate Injection is the most suitable drug for this purpose *epinephrine should not be used* since *phenothiazine derivatives have been found to reverse its action resulting* in a further lowering of blood pressure Patients on trifluprom azine therapy who are undergoing surgery should be watched carefully for possible hypotensive phenomena Moreover it should be remembered that dosages of anaesthetics and central nervous system depressants should be reduced

As with other phenothiazines potentiation of central nervous system depressants (opiates analgesics antihistamines barbiturates alcohol) and of atropine occurs with trifluprom azine

Liver damage as manifested by jaundice or biliary stasis may be encountered Blood dyscrasias including leucopenia agranulocytosis thrombocytopenic purpura eosinophilia and pancytopenia may occur in some patients For this reason routine blood counts are advisable during therapy The patient should be observed for any soreness of the mouth gums or throat or any symptoms of upper respiratory infection If these symptoms occur and confirmatory leucocyte count indicates cellular depression therapy should be discontinued and other appropriate measures should be instituted immediately

The following have never been reported with trifluprom azine although they have occurred with other phenothiazine derivatives Hypotension severe enough to cause fatal cardiac arrest cerebral oedema potentiation of phosphorus insecticides eczema asthma laryngeal oedema angioneurotic oedema and pigmentary retinopathy

Caution The use of phenothiazines as a class is associated with different degrees of drowsiness It is worthwhile to remember that engine crews vehicle drivers and workers in workshops with fast moving parts are advised not to use these drugs while on duty unless recommended and approved by the physician attending on them

Administration and Dosage

Caution The parenteral administration of trifluprom azine may sometimes cause postural hypotension to preclude its occurrence patients should be kept under close clinical supervision in a recumbent position if necessary If severe shock is encountered supportive measures should include intravenous vasopressor drugs such as Levarterenol Bitartrate Injection (Levophed) *epinephrine should not be used*

NAUSEA AND VOMITING

Parenterally adult dosage may range from 1 to 3 mg intravenously or 5 to 10 mg intramuscularly for prophylaxis as well as for treatment Dosage may be repeated after 4 hours if necessary Oral prophylactic dosage may range from 20 to 30 mg daily For elderly or debilitated patients an intramuscular dose of 2 5 mg is suggested For children the recommended dosage is 0 2 mg/kg ($^1/_{10}$ mg/lb) up to a maximum total daily dose of 10 mg

divided into 3 doses orally or a range of 0 2 to 0 25 mg/kg (1/10 to 1/8 mg/lb) up to a maximum total daily dose of 10 mg intramuscularly The drug should not be administered to children under 2 1/2 years of age and is not recommended for intravenous use in children

For the Nausea and Vomiting of Early Pregnancy The suggested dosage is 10 mg orally given before breakfast or at bedtime If required 20 mg daily may be given in divided doses before breakfast and at bedtime

OBSTETRICS

First stage of labour 15 mg intramuscularly plus one half (1/2) the usual dose of a narcotic Dosage may be repeated every 4 hours as indicated In primiparas trifluprornazine should be given when the dilatation of the cervix is 3cm and pains are well established In multiparas dilatation of the cervix should be 5 cm before the drug is given

Second stage of labour 8 mg intravenously before anaesthesia is started The amount of general anaesthesia required is generally greatly reduced when trifluprornazine is given Premedication with one of the belladonna drugs is suggested

PRE AND POST OPERATIVE TRANQUILLIZATION

Intravenous 1 to 3 mg as an initial adult dose if necessary an additional dose of one fourth (1/4) of the amount of the initial dose may be given as soon as desired

Intramuscular 5 to 10 mg as an average initial adult dose if required a second injection may be given but total doses of 20 mg should not be exceeded For elderly or debilitated patients an intramuscular dose of 2 5 mg is suggested For children an intramuscular dosage regimen of 1 mg per year of age up to 10 mg is suggested Some clinicians have employed the intravenous route of administration with great success using a single dose of 2 to 3 mg for children 7 to 14 years of age and 1 to 2 mg intra venously for those under 7 years of age Generally drugs like trifluprornazine are not required for routine use in children under 2 1/2 years of age

ALCOHOLISM

For severely agitated patients an initial intramuscular dose of 20 to 40 mg is recommended repeated if necessary in one or two hours Thereafter oral therapy should be instituted in a range of 10 to 25 mg or more three times per day depending on individual response

ANXIETY AND TENSION

A daily oral dosage schedule of 20 to 50 mg ranging if required up to 80 mg in two divided doses has generally been adequate

MENTAL DISORDERS AND BEHAVIOURAL PROBLEMS

Institutionalized Adult Patients

Optimum dosage levels must be determined individually for each patient The suggested starting dose for oral therapy is 100 to 150 mg daily After treatment is instituted the daily dosage should be adjusted until the desired clinical effect is obtained Continued treatment is necessary to achieve maximum therapeutic benefits In some patients optimum clinical improvement may occur only after prolonged treatment When symptoms are controlled dosage can generally be reduced gradually to maintenance levels

The suggested intramuscular dose is 60 to 150 mg daily In clinical experience to date total daily doses of 150 mg have been well tolerated Daily doses larger than 150 mg should be exceeded with great caution

Non institutionalized Adult Patients

Patients with severe mental disorders should receive the same regimen as outlined for institutionalized patients

Patients on *maintenance therapy* following institutional care are generally benefited by daily oral doses of 30 to 150 mg

Children

As in adult therapy optimum dosage levels must be determined individually for each patient An oral dosage schedule of 30 mg per day ranging if required up to 150 mg daily in divided doses has generally been adequate For maintenance therapy dosage should be increased or decreased to meet individual requirements When intramuscular use is indicated in children the usual range has been 0 2 to 0 25 mg/kg of body weight ($^1/_{10}$ to $^1/_8$ mg per lb)

Senile Psychoses (Including Arteriosclerotic States)

Initial dosage – 10 mg orally two to three times daily adjusted to the response of the patient

Presentation Tablets 10 mg strips of 10 tablets and boxes of 10 strips of 10s 25 mg bottles of 25 and 250

Injections 3 mg/ml and 10 mg/ml 1 ml ampoules in boxes of 5 10 mg/ml 10 ml vials and 20 mg/ml 5 ml vials

Note Solutions of Siquil should be protected against exposure to light The preparation may become somewhat discoloured if exposed to light but this does not indicate any change which would prevent its use However when definite colour changes occur as a result of improper storage the preparation should not be used Store in a cool place

SPECTROCIN® OINTMENT — Ointment

Neomycin Sulphate Gramicidin Ointment

Spectrocin Ointment is a general purpose antibiotic ointment of high qua

lity Each gramme of Spectrocin Ointment contains neomycin sulphate equivalent to 2 5 mg neomycin base and 0 25 mg gramicidin in Plastobase® (Plasticized Hydrocarbon Gel) a polyethylene and mineral oil gel base

Action Most of the organisms responsible for superficial bacterial infections are highly susceptible to neomycin those which are resistant or only slightly susceptible to neomycin are usually susceptible to gramicidin If topical use of an antibiotic causes sensitization subsequent systemic use in that patient may be hazardous Neomycin is rarely administered systemi cally and gramicidin never Therefore even if sensitization to Spectrocin should occur the patient need not be denied the use of valuable antibiotics that are generally used orally or parenterally for serious disorders

Advantages The plasticized hydrocarbon gel used in Spectrocin Ointment pro vides fast regular and thorough release of medicaments and uniform dispersion of medicaments even at elevated temperatures

Consistently soft Spectrocin Ointment is easily applied to the skin and is *non running* at body temperature It imparts a velvety feel to the skin and can be readily removed Spectrocin may be used for patients sensitive to other antibiotics

Indications Spectrocin Ointment is indicated to help in the prevention of super ficial infections of the skin such as occur in minor burns cuts scratches or abrasions

Precautions Substitute alternate specific treatment in case of deep wounds punctured wounds serious burns wounds where marked inflammation persists or infection occurs

Administration and Dosage Apply liberally to affected area two or three times daily or as directed by physician

Presentation Tubes of 15 g

Expiration date 36 months

SPECTROCIN® OPHTHALMIC OINTMENT — Ophthalmic Ointment

Neomycin Sulphate Gramicidin Ophthalmic Ointment

Spectrocin Ophthalmic Ointment (neomycin sulphate gramicidin ophthal mic ointment) is a smooth white ointment containing neomycin sulphate equivalent to 2 5 mg neomycin base and 0 25 mg gramicidin in each gramme of Plastobase® (Plasticized Hydrocarbon Gel) a polyethylene and mineral oil gel base

Action The antibacterial spectrum of neomycin and gramicidin includes gram positive and gram negative organisms responsible for many bacterial in fections of the eye Most organisms causing these infections are highly susceptible to neomycin those which are resistant or only slightly susce ptible to neomycin are usually susceptible to gramicidin

Hypersensitivity reactions to the topical application of neomycin or grami cidin are exceedingly rare However even if sensitivity to these agents

should occur it does not pose a problem in subsequent systemic therapy for the patient since these antibiotics are rarely administered systemically Certain othe valuable antibiotics that are commonly given orally or par enterally for serious disorders can thus be reserved for such use

Advantages Spectrocin Ophthalmic Ointment is easily applied to the eyelid o conjunctiva spreads smoothly and does not melt at body temperature It may be conveniently removed from the eyelid or conjunctiva since it is readily absorbed by cloth or cleansing tissue

Indications Spectrocin Ophthalmic Ointment is indicated for external use in superficial bacterial infections of the eyelids and lid margins blepharitis due to bacterial infection hordeolum superficial bacterial infection of the conjunctiva and cornea and as prophylaxis after extraction of foreign bodies from the eye

Contraindications This preparation is contraindicated in persons with a history of hypersensitivity to any of its ingredients

Adverse Reactions and Precautions The preparation is not intended for the treatment of deep seated infections of the eye Although hypersensitivity reactions to the components are unlikely medication should be discontinued if signs of irritation appear

As with any antibiotic preparation prolonged use may result in overgrowth of nonsusceptible organisms including fungi Constant observation of the patient is essential Should superinfection occur the preparation should be discontinued and/or appropriate therapy instituted

Administration and Dosage Half inch or more of ointment column should be applied to the eyelid or conjunctiva as required usually two or three times a day

Presentation Tubes of 3 6 g with ophthalmic tip

Expiration date 36 months Keep tightly closed in a cool place

SPECTROSULF® DUSTING POWDER — Powder

Neomycin Gramicidin (Spectrocin®) with Sulphacetamide

Spectrosulf Dusting Powder is a fine powder designed for topical application on infected surfaces

Each gramme of Spectrosulf Dusting Powder contains

Sodium Sulphacetamide	75 mg
Neomycin Sulphate (equivalent to pure base)	5 mg
Gramicidin	0 5 mg

Action Spectrosulf Dusting Powder is a broad spectrum antibacterial formulation containing three highly effective antibacterial agents i e sodium sulphacetamide neomycin sulphate and gramicidin Sodium sulphacetamide is non-irritant when applied locally and is active against a broad range of susceptible organisms Neomycin sulphate is specially active against gram negative bacteria viz E coli A aerogenes K pneumoniae Proteus

vulgaris and H influenzae while gramicidin is particularly active against gram positive bacteria e g streptococci staphylococci pneumococci and aerobic sporulating bacilli None of the ingredients of Spectrosulf Dusting Powder is absorbed when applied locally and hence has no untoward effects Spectrosulf Dusting Powder has advantages as it acts in the presence of pus and tissue fluids and does not delay wound healing

Indications Infected ulcers cuts wounds burns pyoderma and other infected dermatoses

Contraindications It is contraindicated in patients who are allergic to sulphacetamide and neomycin

Adverse Reactions Although sensitization reactions to sodium sulphacetamide and neomycin sulphate are rare but have been reported Otherwise Spectrosulf Dusting Powder is devoid of any significant side effects

Administration After cleaning the infected surface sprinkle the powder directly by tapping the bottle gently and then apply sterile bandage

Presentation Spectrosulf Dusting Powder is supplied in plastic bottles of 10 g

Note Keep tightly closed in a cool dry place

Expiration date 24 months

STRYCITAL® Tablets

STRYCITAL® FORTE Tablets

Streptomycin with Phthalylsulphacetamide

Strycital is Streptomycin with Phthalylsulphacetamide supplied as tablets for the control of diarrhoea of bacterial origin

Each Strycital Tablet provides

Streptomycin base (as Sulphate)	0 125 g
Phthaly sulphacetamide	0 250 g

Each Strycital Forte Tablet provides

Streptomycin base (as Sulphate)	0 250 g
Phthaly sulphacetamide	0 500 g

Action Oral administration of a combination of streptomycin and a sulphonamide affords a more rapid and effective sterilization of the intestines than is provided by the administration of either drug alone

Streptomycin is effective against many of the organisms which commonly infect the intestinal tract Since streptomycin is poorly absorbed from the gastrointestinal tract and is not inactivated therein high concentrations of the orally administered antibiotic are reached in the intestinal contents Consequently the enteric flora is markedly inhibited and the bacterial content of the faeces is greatly reduced Oral ingestion of streptomycin is utilized only for local antibacterial effects in the intestinal tract Since oral dosage reduces the intra-intestinal bacterial flora it is of use prophylactically in intestinal surgery and in the treatment of bacillary diarrhoeas

Phthalylsulphacetamide is absorbed only to a negligible extent after oral administration however high concentrations of phthalylsulphacetamide appear in the lumen of the intestine as well as in the tissues of the intestinal wall without concomitant production of significant blood levels or appre ciable tissue concentrations anywhere else in the body High concentra tions of phthalylsulphacetamide in the bowel wall is especially important to ensure optimal antibacterial action against enteric organisms

Indications Strycital Tablets are recommended for the treatment of bacterial enteric infections and diarrhoeal conditions susceptible to phthalylsul phacetamide or streptomycin Specially Strycital Tablets are useful in shigellosis including mild early bacillary dysentery and diarrhoea of non specific origin such as infantile diarrhoea and the summer diarrhoeas It has also been of benefit in controlling acute attacks of ulcerative colitis

If the symptoms of dysentery are not controlled within 5 days a review of the case is desirable In acute fulminating gastroenteritis supportive measures to combat fluid and electrolyte imbalance should be instituted Strycital Tablets are not recommended for the treatment of typhoid fever and systemic infections

Dosage Adults 2-4 tablets of Strycital or 1 2 tablets of Strycital Forte administered 3-4 times a day

Children under 40 kg should be given a total dose of 2 6 tablets of Strycital or 1 3 tablets of Strycital Forte in divided doses according to the body weight and severity of the disease

For the pre-operative sterilization of gastrointestinal tract 4 tablets of Stry cital or 2 tablets of Strycital Forte should be administered 4 times a day for 2-3 days before surgery

Side Effects No unfavourable effects have been reported with Strycital Tablets Evidence of sulphonamide toxicity or local sensitivity reactions to strepto mycin requires discontinuation of treatment

Presentation Strips of 10 tablets and boxes of 10 strips of 10 s

Note Strycital Tablets may be stored at room temperature

Expiration date 24 months

SYNAMOX* **Capsules**

Amoxycillin Trihydrate

Synamox (Amoxycillin Trihydrate) is a semi synthetic penicillin with a broad spectrum antibacterial action It is a bactericidal antibiotic effective against a wide range of gram-positive organisms such as D pneumoniae Strepto coccus Staphylococcus as well as gram negative organisms such as

Gonococcus E coli H influenzae S typhi and P mirabilis Its mechanism of action is similar to that of Penicillin G It is stable in acid medium but it is inactivated by the enzyme penicillinase All strains of Pseudomonas Klebsiella and Enterobacter are resistant to amoxycillin

Pharmacokinetics Synamox is rapidly and completely absorbed from the gastrointestinal tract It is not inactivated by gastric acid and presence of food does not interfere with its absorption Absorption is proprotional to the dose administered

After a single dose of 250 mg or 500 mg of amoxycillin given orally peak plasma concentrations achieved are 4 5 mcg/ml and 7 5 8 mcg/ml respectively within 2 hours In children absorption is quicker and peak concentration is achieved earlier

Synamox is distributed in various tissues and its penetration in bronchial mucosa biliary secretion the middle ear and nasal sinus is excellent In normal individual its penetration in meninges and joints is poor but in presence of inflammation penetration is quite adequate

Synamox is excreted unchanged in an active form in urine The excretion can be delayed by simultaneous administration of probenecid

Indications Synamox is indicated in the treatment of respiratory tract infections due to H influenzae D pneumoniae Streptococci and non penicillinase producing Staphylococci It is also indicated in genitourinary tract infections due to E coli and Gonococci gastrointestinal infection due to Salmonella typhi (enteric fever) also responds to amoxycillin therapy It is also effective in cases of sinusitis otitis media and meningitis caused by H influenzae and other amoxycillin sensitive organisms and in soft tissue infection caused by Streptococci susceptible Staphylococci and E coli

Dosage Dose would depend upon the severity and site of infection The usual recommended adult dose is 250 mg every 8 hrs In severe infections or infections caused by less susceptible organisms a dose of 500 mg every 8 hrs or as advised by the physician may be used

In children the usual recommended dose is 20 mg/kg/day in three divided doses every 8 hrs In severe infections or infections caused by less susceptible organisms a dose of 40 mg/kg/ day in three divided doses every 8 hrs or as advised by the physician may be used For enteric fever a much higher dose of 100 mg/kg/day may have to be employed

Side Effects Synamox is a relatively well tolerated drug As with other penicillins the side effects are mainly related to hypersensitivity reactions and are more likely to be seen in patients previously known to be hypersensitive to penicillin or those having history of allergy asthma hay fever or urticaria Side effects noted are nausea vomiting and diarrhoea glossitis urticaria and skin rashes Anaemia thrombocytopenia leucopenia eosinophilia and agranulocytosis have been reported and are reversible on discontinuation of therapy

Precautions Though rare serious hypersensitivity reaction may occur following oral amoxycillin therapy as with any penicillin It is more likely in patients previously known to be penicillin-sensitive and those having a history of sensitivity to multiple allergens If anaphylactoid reaction develops it

should be treated with epinephrine intravenous steroids intratracheal intubation and administration of oxygen Safety for use of Synamox in pregnancy has not been established

Presentation Synamox is available in the following strengths

Capsule containing amoxycillin trihydrate equivalent to 250 mg of amoxycillin base in vials of 3 capsules and boxes of 10 vials of 3 s

Capsule containing amoxycillin trihydrate equivalent to 500 mg of amoxycillin base in vials of 3 capsules

Expiration date 24 months

SYNAMOX* FOR SYRUP — Powder for Syrup

Amoxycillin Trihydrate

Synamox (Amoxycill n Trihydrate) is a semi synthetic penicillin with a broad spectrum antibacterial action It is a bactericidal antibiotic effective against wide range of gram positive organisms such as D pneumoniae Streptococcus Staphylococcus as well as gram negative organisms such as Meningococcus Gonococcus etc E coli H influenzae and Salmonella typhii are also sensitive to amoxycillin Its mechanism of action is similar to that of Penicillin G It is stable in acid medium but inactivated by the enzyme penicillinase All strains of pseudomonas klebsella and enterobacter are resistant to amoxycillin

Synamox for Syrup (5 ml) contains amoxycillin trihydrate equivalent to 125 ml of amoxycillin

Pharmacokinetics Synamox is rapidly and completely absorbed from gastrointestinal tract It is not inactivated by gastric acid secretion and presence of food does not interfere with absorption The absorption is proportional to the dose administered

Synamox is distributed in various body tissues and its penetration in bronchial mucosa biliary secretion the middle ear and nasal sinus fluid is excellent In normal patients its penetration in meninges and joints is poor but in presence of inflammation its penetration in those tissues is quite adequate

Synamox is excreted unchanged in an active form in the urine The excretion can be delayed by simultaneous administration of probenecid

Indications Synamox is indicated in treatment of respiratory tract infections due to H influenzae Streptococci and non penicillinase producing Staphylococci It is also indicated in genitourinary tract infections due to E coli and Gonococci Gastrointestinal infections due to Salmonella typhii also respond to amoxycillin therapy It is also effective in cases of sinusitis otitis media and in cases of meningitis by H influenzae

Reconstitution of Syrup Add a small volume of water which is boiled and cooled to the contents of the bottle and shake well Again add small volumes of such water till the volume reaches the given mark on the bottle

This will constitute 30 ml of fruit flavoured syrup The enclosed spoon in the pack measures 5 ml which when given will provide 125 mg of amoxycillin The total volume of 30 ml gives six such doses The reconstituted syrup should be used up within 5 days

Dosage Children 20 mg/kg/day in three divided doses Children weighing 20 kg or more may be given the adult dose

Side Effects Side effects may be observed in hypersensitive patients in the form of gloss tis stomatitis black hairy tongue nausea vomiting diarrhoea skin rashes urticaria exfoliative dermatitis erythema multiforme Anaphylaxis has been reported Anaemia thrombocytopenia eosinophilia leucopenia and agranulocytosis have been reported and are reversible on discontinuation of therapy

Precautions Synamox is contraindicated in patients who are hypersensitive to penicillin It should also be used cautiously in patients who have a history of sensitivity to multiple allergens If anaphylactoid reaction develops it should be treated with epinephrine intravenous steroids intratracheal intubation and administration of oxygen Safety for use of Synamox in pregnancy has not been established

Presentation Granular powder for Syrup containing Amoxycillin trihydrate equivalent to 125 mg of amoxycillin per 5 ml in bottles of 30 ml with 5 ml spoon measure

Expiration date 18 months

TALSUTIN® VAGINAL TABLETS — Vaginal Tablets

Tetracycline and Amphotericin B Fungizone®

Talsutin Vaginal Tablets are available as compressed tablets containing tetracycline base equivalent to 100 mg tetracycline hydrochloride and 50 mg amphotericin B for intravaginal administration

Action Talsutin Vaginal Tablets combine a broad spectrum antibiotic with an antifungal agent and are designed to provide simultaneous antimicrobial anticandidal and antitrichomonal therapy

Tetracycline has proved effective therapeutically against a broad spectrum of micro organisms including both gram positive and gram negative bacteria spirochaetes and certain rickettsiae and viruses While the direct action of tetracycline against *Trichomonas in vitro* is slight it acts against the bacteria with which *Trichomonas* often exist in symbiosis *in vivo*

Amphotericin B is a polyene antibiotic with antifungal activity against a wide variety of yeasts and yeast-like fungi including *Candida* species Produced by a strain of *Streptomyces nodosus* Amphotericin B exhibits greater activity *in vitro* than nystatin against *Candida* (Monilia) *albicans*

Indications Talsutin Vaginal Tablets are indicated in the treatment of candidal trichomonal and/or bacterial infections of the vagina and cervix The pre

paration is also useful in the prevention of secondary infections following cervical cauterization and conization in the treatment of infectious complications of atrophic or senile vaginitis in non specific vaginitis and in vaginal infections in which an offending organism cannot be identified

Contraindications The preparation should not be administered to patients with a history of hypersensitivity to any of its components

Precautions Appropriate measures should be taken to avoid the possibility of reinfection by the sexual partner

Adverse Reactions Talsutin Vaginal Tablets are virtually nontoxic and non sensitizing and are usually well tolerated If irritation occurs treatment should be discontinued

Dosage and Administration The usual therapeutic dose is one or two tablets daily deposited high in the vagina In most cases two weeks of therapy will be sufficient but more prolonged treatment may be necessary It is important that therapy be continued during menstruation Adjunctive measures such as therapeutic douches are unnecessary and sometimes inadvisable Cleansing douches may be used by non pregnant women if desired for aesthetic purposes

If hanging drop preparations or cultures remain positive after one course of therapy a second or even third course may be given

The usual prophylactic dose following cervical cauterization or conization is one tablet daily at bedtime for one week or as required

Presentation Talsutin Vaginal Tablets are supplied in strips of 4 tablets and boxes of 6 strips of 4 s

Note Store in a cool dry place

Expiration date 18 months

THERAGRAN® Tablets

Vitamins for Therapy

Theragran Tablets are indicated in the oral treatment of mixed vitamin deficiencies

Each Theragran Capsule shaped Tablet supplies

Vitamin A	25 000 I U
Vitamin D	1 000 I U
Vitamin B_1 (Thiamine Mononitrate)	10 mg
Vitamin B_2 (Riboflavine)	10 mg
Niacinamide	100 mg
Vitamin C (as Sodium Ascorbate)	0 2 g
Vitamin B_6 (Pyridoxine Hydrochloride)	5 mg
Calcium Pantothenate	20 mg
Vitamin B_{12} (as B_{12} activity concentrate oral powder)	5 mcg
Vitamin E (as d-α- Tocopheryl Acid Succinate)	15 I U

Advantages Theragran is the most widely recommended high potency vitamin preparation in the world The formulation is reviewed constantly to assure inclusion of nutritional agents that are known to be important when the patient s physical condition requires nutritional support

Indications Theragran Tablets supply truly therapeutic dosages of ten vitamins almost invariably associated with chronic vitamin-deficiency states and of clinical importance whenever nutritional support is required Clinical research and experience support the use of nutritional therapy in the following acute or chronic situations Infectious disease arthritis hepatic disease the mal absorption syndrome degenerative disease cardiac disease dermatologic conditions gastrointestinal conditions (including peptic ulcer) neuroses and psychiatric disorders diabetes alcoholism ulcerative colitis pancreatitis osteoporosis the female climacteric and pre and post operatively

Dosage One tablet daily or as indicated

Presentation Bottles of 15 and 100 tablets

Note Keep tightly closed in a cool place

Expiration date 18 months

THERAGRAN® PEDIATRIC DROPS — Liquid

Multiple Vitamin Drops

Theragran Pediatric Drops Multiple Vitamin Drops is a pleasant tasting fruit-flavoured solution preserved with 0 1% sodium benzoate and 0 02% methyl parahydroxybenzoate containing balanced amount of the essential vitamins in a convenient drop-dosage form Because of its palatability Theragran Pediatric Drops are well accepted by infants and children

Each 0 6 ml supplies

Vitamin A	5 000 IU
Vitamin D_3	1 000 IU
Vitamin B_1 (Thiamine Hydrochloride)	1 2 mg
Vitamin B_2 (as Riboflavine 5 Phosphate Sodium)	2 0 mg
Vitamin B_6 (Pyridoxine Hydrochloride)	2 0 mg
Vitamin C	70 0 mg
Niacinamide	12 0 mg
d Panthenol	5 0 mg

Indications Deficiencies of a single vitamin are practically impossible in infants and children since most nutritional deficiency states involve multiple fa ctors If a patient is deficient in one vitamin he is invariably deficient in other essential vitamins Because of its high content of various vitamin compo nents Theragran Pediatric Drops are particularly useful in infants and children in preventing and treating rickets scurvy beriberi pellagra and a wide variety of other syndromes caused by metabolic disturbances in connection with the various avitaminoses It is also recommended for prophylactic use in patients with an inadequate vitamin intake in cases

where vitamin requirements have increased or in patients whose condition is such that vitamin absorption and utilization are impaired

Theragran Pediatric Drops are especially valuable during convalescence and during periods of active development of tissue repair

Advantages Theragran Pediatric Drops are convenient to give and easy to take It mixes easily with milk soups cereals puddings and juices or it may be placed directly on the tongue Also it will not change the taste of food appreciably (if at all) and can often be given without the patient's knowledge thus surmounting the psychological barrier to medication so often encountered in paediatrics This dosage form is particularly suited for infants children and patients who have difficulty in taking tablets and/or capsules

Dosage Prophylactic Dose 0 3 ml daily for infants and children up to 4 years
0 6 ml daily for older children

Therapeutic Dose As directed by the physician

Presentation Bottles of 10 ml with dropper scored at 0 3 ml and 0 6 ml

Note Keep in a cool place

Expiration date 12 months

THERAGRAN GR®

Tablets

Anabolic Sex Hormones with Vitamins and Minerals

Theragran GR (Anabolic Sex Hormones with Vitamins and Minerals) is an oral preparation providing full therapeutic amounts of anabolic steroid hormones in an optimally balanced combination It also contains fully protective amounts of vitamins for comprehensive nutritional support with added minerals

Each Theragran GR Tablet contains

ANABOLIC SEX HORMONES	
Ethinyl Oestradiol	8 mcg
Methyltestosterone	4 mg
VITAMINS	
A (as Acetate)	2500 U S P units
B_1 (Thiamine Mononitrate)	2 5 mg
B_2 (Riboflavine)	1 5 mg
B_6 (Pyridoxine Hydrochloride)	1 mg
B_{12} (as Cyanocobalamin)	1 mcg
C (as Sodium Ascorbate)	37 5 mg
Calcium Pantothenate	2 5 mg
D (Ergocalciferol)	250 U S P units
E (as d-α- Tocopheryl Acid Succinate)	2 5 I U
Folic Acid	0 1 mg
Niacinamide	10 mg

MINERALS	
Copper (as Sulphate)	0 5 mg
Iodine (as Potassium Iodide)	0 05 mg
Iron elemental (as dried Ferrous Sulphate)	5 mg
Magnesium (as Oxide)	3 mg
Manganese (as Sulphate)	0 5 mg
Zinc (as Sulphate)	0 5 mg

Action The androgen oestrogen ratio in Theragran GR Tablets has been designed to provide the closest approximation of endogenous hormone production Theragran GR provides greater stimulation of anabolic and hormone homeostatic processes with less likelihood of undesired effects than does therapy with either androgen or oestrogen alone

Androgen and oestrogen have opposing effects on the genital and accessory sexual structures of men and women The balanced androgen oestrogen ratio of Theragran GR reduces to a minimum the occurrence of unwanted effects such as masculinization of the female and feminization of the male

The complementary stimulatory actions of the two steroids in Theragran GR offer an increased potential for the anabolism of protein and osseous tissues and for the maintenance of the psychic and nervous system equilibrium at the physiological level of the well adjusted mature man or woman

The separate inhibitory actions of the two steroids on gonadotropic hormone production and release assure an increased potential for the correction of hormonal imbalance such as exists during the climacteric state Theragran GR helps check the hot flushes sweating insomnia headache and peripheral circulatory disturbances associated with the female climacteric In the male climacteric Theragran GR helps the patient maintain psychic equilibrium

Vitamins with added minerals have been included in the formula to help the body meet the increased demand for these essentials during anabolism Because Theragran GR contains fully protective amounts of vitamins elderly patients in particular will benefit from this comprehensive nutritional support and since the diets of such patients are frequently inadequate they commonly have a greater need for vitamin mineral supplementation than any other age group

Indications Theragran GR is indicated–

1 During and following the menopause for prompt relief from the clinical symptoms of the menopause such as emotional instability hot flushes sweating insomnia headaches and peripheral vascular disturbances The sequelae of the menopause while often less striking than the early symptoms may be far more distressing and damaging The lowered supply of anabolic steroids following the menopause may be inadequate to provide for the metabolic needs of protein and osseous tissues

2 During and following the male climacteric

3 Tissue atrophy and/or mild psychic disturbances in geriatric patients

4 Protein depletion and chronic debility following malnutrition infection trauma surgery or prolonged illness in geriatric patients

5 Osteoporosis (postmenopausal senile and other types)

Contraindications Theragran GR is not recommended for patients with a history of established or suspected mammary or genital (including prostatic) malignancy

Precautions While folic acid may correct the blood picture of pernicious anaemia it may not ameliorate the attendant neurologic involvement The possibility of this condition should be excluded before treatment

Adverse Reactions When administered in therapeutic dosage Theragran GR generally produces a minimum of undesired effects However because the normal endogenous hormonal production and tissue responsiveness vary individually certain patients may be overly reactive to either androgenic or oestrogenic medication

Unwanted effects (virilization uterine bleeding mastodynia) may be controlled by temporarily reducing dosage or by discontinuing medication entirely

Patients receiving steroid medication should also be observed for oedema This may be combated by temporarily reducing or omitting the medication by instituting a low salt diet o by the use of a suitable diuretic

Dosage The average adult dosage is 2 tablets daily Dosage should be increased or lowered in accordance with individual response

When Theragran GR is used to continue the benefits of long acting parenteral androgen oestrogen therapy the oral medication should be started three weeks after the time of the last injection or before this if symptoms have reappeared When parenteral androgen oestrogen therapy is given to replace Theragran GR the oral medication may be continued for two or three more days following the initial injection

Presentation Strips of 10 tablets and boxes of 10 strips of 10 s

Note Keep in a cool place

Expiration date 18 months

THERAGRAN M® — Tablets

Vitamins Minerals for Therapy

A high potency vitamin formula with added minerals and trace elements

Each Theragran M Capsule shaped Tablet contains

VITAMINS	
Vitamin A	25 000 I U
Vitamin D	1 000 I U
Vitamin C	200 mg
Thiamine Mononitrate (B_1)	10 mg
Riboflavine (B_2)	10 mg
Niacinamide	100 mg
Pyridoxine Hydrochloride (B_6)	5 mg

Calcium Pantothenate	20 mg
Vitamin E	15 I U
Cyanocobalamin (B_{12})	5 mcg
MINERALS	
Potassium Iodide (equivalent to 0 15 mg Iodine)	0 2 mg
Dried Ferrous Sulphate (equivalent to 12 mg Iron)	41 mg
Copper Sulphate (equivalent to 2 mg Copper)	8 mg
Manganese Sulphate (equivalent to 1 mg Manganese)	2 8 mg
Magnesium Carbonate (equivalent to 65 mg Magnesium)	270 mg
Zinc Sulphate (equivalent to 1 5 mg Zinc)	6 6 mg

Action and Uses Theragran-M is indicated in mixed vitamin and mineral deficiencies Theragran M supplies high potency dosages of vitamins and minerals associated with chronic vitamin deficiency states and is of clinical importance when high potency nutritional support is indicated in special medical situations such as infectious disease arthritis hepatic disease the malabsorption syndrome degenerative disease cardiac disease dermatologic conditions gastrointestinal conditions (including peptic ulcer ulcerative colitis) psychiatric disorders diabetes alcoholism pancreatitis osteoporosis menopause and pre and post-operatively

Dosage Adults and older children 1 tablet daily or as recommended

Presentation Strips of 10 tablets and boxes of 10 strips of 10 s

Note Keep in a cool place

Expiration date 18 months

THERAGRAN® SYRUP — Syrup

Multivitamin Tonic with Lysine and Iron

Theragran Syrup is a pleasantly flavoured multivitamin tonic fortified with especially formulated lysine and iron for children It can be recommended for patients who prefer a liquid preparation

Each 5 ml of Theragran Syrup provides

Vitamin A (as Palmitate)	3 000 I U
Vitamin D_3	500 I U
Thiamine Hydrochloride (B_1)	1 5 mg
Vitamin B_2 (as Riboflavine 5-Phosphate Sodium)	1 5 mg
Niacinamide	10 mg
Pyridoxine Hydrochloride (B_6)	1 mg
d Panthenol	2 5 mg
Cyanocobalamin (B_{12})	5 0 mcg
Vitamin C	50 mg
Lysine Monohydrochloride	100 mg
Ferrous Gluconate	26 mg

In a pleasantly flavoured syrup base (Extra vitamins added to compensate for loss on storage)

Action and Uses Theragran Syrup is designed to supply essential vitamins It provides nutritional support and is indicated in mixed vitamin deficiencies

It is of particular value in special medical conditions such as infectious dis ease hepatic disease malabsorption syndromes improper food intake or utilization and in physiological conditions where increased amounts of essential vitamins are required Theragran Syrup is also useful as a general daily dietary supplement for prophylaxis of vitamin deficiencies Besides extra essential vitamins children need adequate amounts of lysine and iron for their proper growth Theragran Syrup provides both and hence is an ideal tonic for the optimum growth and development of adolescent

Dosage For children between 2 12 years one teaspoonful (5 ml) once or twice a day is recommended As a dietary supplementation one teaspoonful daily is adequate

Presentation Bottles of 60 ml

Note Keep tightly closed in a cool place Protected from light

Expiration date 15 months

TOLAC® — Tablets

Testolactone

Tolac (Testolactone) contains testolactone which is chemically designated as D Homo 17 a oxaandrosta 1 4-diene 3 17 dione (1 dehydrotesto lactone or Δ^1 testololactone) Testolactone is a white odourless crystal line solid soluble in ethanol and slightly soluble in water

Tolac is available for oral administration as tablets each containing 50 mg testolactone

Action The precise mechanism by which testolactone produces its clinical antineoplastic effects is unknown at present

Although the chemical configuration of testolactone is similar to that of certain androgenic hormones it is devoid of androgenic activity in the doses commonly employed

Tolac was found to be effective in approximately 15% of patients with advanced or disseminated mammary cancer evaluated according to the following criteria 1) Those with a measurable decrease in size of all demonstrable tumour masses 2) Those in whom more than 50% of non osseous lesions decreased in size although all bone lesions remained static and 3) Those in whom more than 50% of total lesions improved while the remainder were static

Indications Tolac (Testolactone) Tablets are recommended as adjunctive therapy in the palliative treatment of advanced or disseminated breast cancer in postmenopausal women when hormonal therapy is indicated It may also be used in women who were diagnosed as having had dissemi

nated breast carcinoma when premenopausal in whom ovarian function has been subsequently terminated

Contraindications (i) Breast cancer in men
(ii) It should not be used during pregnancy

Precautions Plasma calcium levels should be routinely determined in any patient receiving therapy for mammary cancer particularly during periods of active remission of bony metastases If hypercalcaemia occurs appropriate measures should be instituted

Adverse Reactions Maculopapular erythema increase in blood pressure para esthesia aches and oedema of the extremities glossitis anorexia nausea vomiting alopecia and nail growth disturbance are reported Whether they are due to underlying disease or drug-administered is not still dicided

Dosage and Administration Oral dose of 50 mg q i d is recommended This dose can be raised up to 250 mg q i d Therapy should be continued for minimum three months to evaluate response unless there is active pro gression of the disease

Presentation Strips of 10 tablets and boxes of 10 strips of 10 s

Note May be stored at room temperature Avoid exposure to excessive heat

Expiration date 24 months

TOSSEX® IMPROVED — Syrup

Antitussive – Expectorant

Tossex Improved is a cough syrup which contains different beneficial ingredients for relief from cough including the potent antitussive agent codeine phosphate

Each 5ml of Tossex Improved contains

Codeine Phosphate	10 00 mg
Ephedrine Hydrochloride	7 50 mg
Sodium Citrate	75 00 mg
Chlorpheniramine Maleate	4 00 mg
Menthol	1 50 mg
Chloroform	0 02 ml
Ethyl Alcohol	0 15 ml

in a pleasantly flavoured syrup base

Action Codeine phosphate one of the most potent antitussive agents in Tossex Improved acts on cough centre and relieves the irritating cough very effectively Chlorpheniramine maleate checks the allergenic compo nent of cough by counteracting histamine induced congestion and bron chospasm at the same time causing minimum drowsiness Ephedrine relieves the bronchospasm and thereby helps to increase the relief to the patient Ephedrine also acts as a decongestant and decreases nasal stuf finess and helps breathing due to dilation of airway Sodium citrate reduces

the viscosity of bronchial secretions facilitating their easy expulsion Menthol soothens the irritated and inflamed mucosa due to its local anaesthetic effect while chloroform will help to loosen the bronchial secretion

Indications Tossex Improved is indicated in different conditions associated with productive and nonproductive cough Thus it is beneficially used for symptomatic relief of cough in laryngitis pharyngitis tracheobronchitis bronchitis common cold pertussis bronchial asthma croup tuberculosis emphysema bronchopneumonia pneumonia etc

Advantages Tossex Improved provides a well balanced formula

- The most potent antitussive agent – Codeine phosphate
- Decongestant and gentle bronchodilator – Ephedrine hydrochloride
- Soothing agents – Menthol and Chloroform
- Expectorant–Sodium citrate
- Antihistamine–Chlorpheniramine maleate

Side Effects In symptomatic management of cough Tossex Improved usually does not cause side effects It may cause constipation due to codeine phosphate Chlorpheniramine maleate may induce mild drowsiness in some patients which is counteracted by ephedrine

Dosage

Adults One teaspoonful (5 ml) three or four times a day or as directed by the physician

Children Half teaspoonful three or four times a day or as directed by the physician

Direction for use

1 Replace the pilferproof cap of the bottle with the cherry shaped pourer with spoon on the top

2 Detach the spoon to pour the syrup and put it back after use

3 The pourer is designed to control flow of the syrup without spilling and the spoon is to give a measured dose

Presentation Tossex Improved is supplied in 100 ml bottles containing the pourer with a spoon on the top

VIGRAN® with B_{12} — Capsules

Vitamins for Maintenance

A multivitamin preparation for routine use as a dietary supplement in the prevention of vitamin deficiencies

Each Vigran Capsule supplies the following vitamins

Vitamin A	5 000 IU
Vitamin D	500 IU
Thiamine Mononitrate	2 mg
Riboflavine	2 mg
Pyridoxine Hydrochloride	0 5 mg

Pantothenic Acid (as Calcium Pantothenate)	1 mg
Niacinamide	20 mg
Ascorbic Acid	45 mg
Vitamin B_1	2 mcg

Indications Vigran is used as a supplement to the diet for the prevention of deficiencies of these vitamins

Dosage One capsule daily

Presentation Bottles of 25 and 100 capsules

Note Keep in a cool place

Expiration date 24 months

VIMGRAN®

Tablets

Multiple Vitamins Minerals Tablets

Vimgran is a vitamin and mineral formula for maintenance Each Vimgran tablet provides 100% or more of the minimum daily requirements vitamins A B_1 B_2 C D and niacinamide for adults and children as well as other vitamins plus minerals and trace elements caloric equivalent is 2 calories per tablet

Each Vimgran Tablet contains

VITAMINS

Vitamin A (as Acetate)	5 000 IU
Vitamin D (Irrad Ergosterol)	500 IU
Vitamin B_1 (Thiamine Mononitrate)	3 0 mg
Vitamin B_2 (Riboflavine)	3 0 mg
Vitamin B_6 (Pyridoxine Hydrochloride)	1 0 mg
Vitamin B_{12} (Cyanocobalamin)	2 0 mcg
Calcium Pantothenate	5 0 mg
Niacinamide	20 0 mg
Vitamin C (as Sodium Ascorbate)	50 0 mg
Vitamin E (as d α Tocopheryl Acid Succinate)	5 IU
Folic Acid	0 1 mg

MINERALS

Calcium Carbonate (equi to 100 mg Calcium)	250 mg
Ferrous Sulphate exsiccated (equi to 10 mg Iron)	34 mg
Potassium Iodide (equi to 0 15 mg Iodine)	0 2 mg
Potassium Sulphate (equi to 5 mg Potassium)	11 0 mg
Copper Sulphate (equi to 1 mg Copper)	4 0 mg
Manganese Sulphate (equi to 1 mg Manganese)	2 8 mg
Zinc Sulphate (equi to 1 5 mg Zinc)	6 6 mg
Magnesium Oxide (equi to 6 mg Magnesium)	10 0 mg

Advantages Vanillin coated tablet minimizes vitamin taste Vitamin after taste occurs rarely

Indications To help prevent vitamin and mineral deficiencies

Dosage One tablet daily or as recommended

Presentation Strips of 10 tablets and boxes of 3 strips of 10 s

Expiration date 18 months

XIDOX* — Capsules

Doxycycline Hydrochloride

Xidox is Doxycycline Hydrochloride a broad spectrum antibiotic synthetically derived from oxytetracycline The chemical composition of doxycycline hydrochloride is alpha 6 deoxy-5 oxytetracycline

Pharmacokinetics Xidox (Doxycycline Hydrochloride) is virtually completely absorbed after oral administration Plasma concentrations are equivalent whether given by oral or parenteral route Food does not interfere with the absorption of Xidox (Doxycycline Hydrochloride) Biliary concentration of doxycycline may be at least 5-10 times higher than that in plasma Doxycycline can penetrate various body fluids and tissues however the concentration in CSF is usually 1/4th that of plasma Within 2 hours of administration it is well distributed in all the tissues of the body

Up to 90% of Xidox (Doxycycline Hydrochloride) in the circulation is bound to plasma protein The biological half life of Xidox (Doxycycline Hydrochloride) is 15 hours after a single dose and 22 hours after repeated doses Studies have shown no significant difference in serum half-life of doxycycline in normal individuals and in those with impaired renal function Haemodialysis does not alter serum half life Xidox (Doxycycline Hydrochloride) is slowly excreted mainly in the urine but is reported not to accumulate in patients with renal impairment Greater absorption and slower rate of excretion permit Xidox (Doxycycline Hydrochloride) to be administered on once a day dosage

Pharmacodynamics Xidox (Doxycycline Hydrochloride) is closely related to tetracycline in its antimicrobial spectrum Xidox is primarily bacteriostatic and is thought to exert its antimicrobial effect by inhibition of protein synthesis Xidox is active against a wide range of gram-positive and gram negative organisms and some large viruses

Indications Xidox (Doxycycline Hydrochloride) is found to be very effective as an antibiotic in a wide variety of infections

Respiratory Infections Bronchitis Bronchiectasis Lung abscesses Pneumonia

Genitourinary Tract Infections Pyelonephritis Cystitis Urethritis etc

Gastrointestinal Tract Infections Enterocolitis Cholecystitis Peritonitis Salmonellosis Shigellosis Cholera Intestinal amoebiasis Prophylaxis for abdominal particularly intestinal surgery

Ear Nose and Throat Infections Tonsillitis Sinusitis Otitis media

Dermatological Soft Tissue Infections Acne vulgaris Impitigo Furuncu losis Infected burns Infected dermatoses Post-operative wounds etc

Gynaecological and Obstetrical Infections Acute puerperal infections and pelvic inflammatory diseases

Venereal Diseases Gonorrhoea Syphilis Chancroid and Granuloma ingui nale (when patient is sensitive to penicillin)

Other Infections Gas gangrene Leptospirosis Osteomyelitis Psittacosis Rickettsial infections Brucellosis Actinomycosis resistant P falciparum malarial infection

Contra ndications This drug is contraindicated in persons who have shown hypersensitivity to any of the tetracyclines

Dosage The dose of Xidox (Doxycycline Hydrochloride) for adults is 100 mg every 12 hours followed by 100 mg once a day or twice a day when infection is severe Grown up children should be given 5 mg/kg pe day divided into two equal doses given at 12 hour interval during first day after this a single dose of half the amount is administered in serious cases the same dose is given every 12 hours

Side Effects The following side effects may occur in patients receiving doxy cycline Gastrointestinal anorexia nausea vomiting diarrhoea glossitis dysphagia enterocolitis and inflammatory lesions (with monilial over growth) in the anogenital egion and photosensitivity reactions Because of virtually complete absorption of Xidox (Doxycycline Hydrochloride) side effects of the lower bowel particularly diarrhoea have been infrequent

Warning Like other tetracyclines Xidox (Doxycycline Hydrochloride) should not be administered to pregnant women and young children unless there is compelling reason to do so

Precautions All infections due to group A beta haemolytic streptococci should be treated for at least 10 days

Presentation Xidox is supplied in vials of 4 capsules each capsule containing doxycycline hydrochloride equivalent to doxycycline 100 mg

Expiration date 36 months

ZIL* 150 mg **Tablets**

ZIL* 300 mg **Tablets**

Tinidazole

Zil (Tinidazole) is highly potent broad spectrum antiprotozoal drug Zil (Tini dazole) tablets provide ethyl 1 [2 (Ethylsulphonyl) ethyl] 2 methyl 5 nitroimidazole a derivative of nitroimidazole for oral administration It has the advantages of (1) Greater efficacy (2) Better tolerance and (3) More convenient dosage schedule over metronidazole

Pharmacokinetics Zil (Tinidazole) is well absorbed from the gastrointestinal tract and peak serum levels occur one to two hours after taking the oral dose

After a single oral dose of 2 g the mean peak serum concentration of Tinidazole is 51 mcg/ml Under the same conditions the mean peak serum concentration of metronidazole is 40 mcg/ml As compared to metronida zole the decline of serum concentration of Tinidazole is much slower The biological half life of Tinidazole is 12 5 hrs and that of metronidazole is 6 2 hrs The difference in half lives of these two drugs result in significant difference in serum concentration 6 hrs after administration of oral dose At the end of 24 hrs the serum concentration of Tinidazole is three times that of metronidazole

Table 1 gives mean half lives of Tinidazole and metronidazole after a single oral dose of 2 g and 0 2 g

TABLE 1

Dose in g	2	0 2
Tinidazole half life (hrs)	12 5 0 5	12 2 0 8
Metronidazole half life (hrs)	7 3 0 5	7 2 0 8

Table 2 gives serum concentrations of these two drugs after a single oral dose of 2 g in 12 healthy female volunteers

TABLE 2

Time (hours)	Concentration (mcg/ml + S E M)	
	Tinidazole	Metronidazole
0 5	23 ± 5	35 ± 6
1	41 ± 5	40 ± 5
2	51 ± 4	39 ± 4
4	46 ± 4	38 ± 2
6	42 ± 3	32 ± 2
24	19 ± 2	5 7 ± 0 8
48	4 2 ± 0 6	0 9 ±
72	1 3 ± 0 1	Not detected

Because of the longer half life as compared to metronidazole Tinidazole can be given in doses spread over longer intervals

Toxicity Studies The safety of Tinidazole is well established Experiments of Tinidazole in mice dogs and monkeys for a period of 6 months did no reveal any acute subacute or chronic toxicity when administered in the dosage of as much as 800 mg/kg of body weight as judged by various clinical biochemical histological and electrocardiographic criteria

Spectrum of Activity Zil (Tinidazole) is a broad spectrum antiprotozoal agent and is active against following protozoa namely T vaginallis T foetus E histolytica E tenella H meleagridis and G lamblia

Indications

Amoebiasis Zil (Tinidazole) is highly effective in both intestinal and extra intestinal amoebiasis As compared to metronidazole the clinical improvement as well as parasitic cure rate is achieved in much shorter time Another advantage of Zil (Tinidazole) over metronidazole in the treatment of amoebiasis is a more convenient dosage form i e twice a day instead of thrice a day

Several comparative clinical trials with Tinidazole and metronidazole in intestinal and hepatic amoebiasis in our country have consistently shown better results with Tinidazole

Trichomoniasis Zil (Tinidazole) is 4 to 16 times more potent than metronidazole as a trichomonicidal agent

Giardiasis Efficacy of Zil (Tinidazole) in giardiasis has been demonstrated in several clinical trials A total single dose therapy as well as twice a day therapy has given almost 100% cure rates

Tolerance Zil (Tinidazole) is well tolerated Only occasionally nausea or bitter taste has been complained by patients As compared to metronidazole gastrointestinal side effects are much less

Dosage

Adults

Intestinal Amoebiasis 600 mg twice a day for 5 days or single daily dose of 2 g for 2-3 days Twice a day dosage treatment with 600 mg may be extended to 10 days in those cases where complete clinical or parasitological cure is not achieved at the end of 5 days

Amoebic Liver Abscess A single dose of 2 g per day for 2 to 3 days

Trichomoniasis 150 mg twice a day for 7 days or 150 mg thrice a day for 5 days or as a single dose of 2 g Treatment of consorts is advised

Giardiasis Same as Intestinal amoebiasis

Children

Intestinal Amoebiasis	50-60 mg per kg body weight to be given once daily for 3 days
Hepatic Amoebiasis	50-60 mg per kg body weight for five days
Giardiasis	A single dose of 50 75 mg per kg body weight

Precautions Zil (Tinidazole) is contraindicated in patients with neurological diseases or with blood dyscrasias It should not be given to nursing mothers or in the first trimester of pregnancy

Presentation

Zil 150 mg	Each tablet containing 150 mg tinidazole Strips of 10 tablets and boxes of 10 strips of 10 s
Zil 300 mg	Each tablet containing 300 mg tinidazole Strips of 10 tablets and boxes of 10 strips of 10 s

ZINEPRESS* Tablets

Hydralazine Hydrochloride

Zinepress (Hydralazine Hydrochloride) is chemically 1 Hydrazinophtha lazine Hydrochloride It is indicated in the management of essential hyper tension usually in combination with other antihypertensive agents

Pharmacokinetics Zinepress is rapidly absorbed when given orally It under goes first pass metabolism in the liver Acetylation is a major route of inactivation and hence rapid acetylators have lower bioavailability (about 30%) than slow acetylators (about 50%) The simultaneous ingestion of food increases the bioavailability of Zinepress The elimination half life of Zinepress from plasma ranges from 2-8 hours (averaging about 3 hours)

Pharmacodynamics Antihypertensive action of Zinepress is due to a direct relaxing effect upon the involuntary muscles of the precapillary arterioles This action is more pronounced on the vasculature of coronary cerebral splanchnic and renal circulation while less pronounced on the vasculature of skin and muscle Diastolic blood pressure is decreased more than the systolic blood pressure Heart rate stroke volume and cardiac output are increased due to reflex sympathetic stimulation Postural hypotension is minimum

The intensity and duration of the antihypertensive action is proportional to the dose of Zinepress (Hydralazine Hydrochloride) The antihypertensive action develops within 1 hour and is seen both in upright as well as supine position If used alone it can lower the mean arterial blood pressure by 25 mm Hg depending upon the dosage

Glomerular filtration renal tubular function and urine volume are not much affected by Zinepress

Indications

1 As an adjunct to other antihypertensive agents in management of benign hypertension
2 In renal hypertension especially in the management of hypertensive crisis in acute glomerular nephritis
3 In hypertension associated with pregnancy
4 Recently Zinepress has been successfully used in the management of resistant cases of congestive cardiac failure The probable mechanism of action is by reduction of after load

Contraindications Coronary artery diseases mitral valvular rheumatic heart disease systemic lupus erythematosus and in patients known to be hyper sensitive to Zinepress

Dosage The usual oral dose of Zinepress varies from 100 200 mg/day Treatment is usually started with small dose of 25 mg twice a day for the first 2 4 days and then increased to 50 mg twice a day from 5th to 7th day This dose is usually sufficient but may be increased if desired It has been noted that if hydralazine is given in daily dose up to 200 mg the incidence of systemic lupus erythematosus-like syndrome is negligible If higher dose is required it is advisable to combine Zinepress with Corbeta (Propranolol Hydrochloride)

Untoward Effects The adverse effects of Zinepress are usually reversible o reduction of the dose however in some cases it may be necessary t discontinue the drug Side effects frequently encountered are headache palpitation anorexia nausea dizziness and sweating Side effect which occur less frequently consist of nasal congestion flushing lacrima tion conjunctivitis paraesthesia oedema tremors and muscle cramp Zinepress given in the manner recommended above may develo tolerance to some of the side effects Untoward effects such as drug feve urticaria skin rash polyneuritis gastrointestinal haemorrhage anaemi and pancytopenia are rare and require termination of Zinepress therapy Pyridoxine is usually helpful in cor ecting peripheral neuropathy caused b Zinepress Zinepress can also induce anginal attacks which can be preven ed by concurrent use of Corbeta Zinepress induced lupus like syndrom occurs in 10 20% of patients who receive prolonged therapy at dose exceeding 400 mg/day The mechanism producing this untoward effect i obscure but genetic and pathophysiological factors have been implicatec The syndrome occurs almost exclusively in patients who are slov acetylators The lupus syndrome is reversible In order to detect L E syndrome at the earliest complete blood count and estimation of ant nuclear antibody titre are undertaken periodically during prolonged therapy particularly when patients develop arthralgia fever chest pain continue malaise or other unexplained signs or symptoms

Precautions

1 Simultaneous use of Monoamine oxidase (MAO) inhibitors

2 Pregnancy

3 Patients who are suspected to have coronary artery disease and blooc dyscrasias

Presentation Each Zinepress Tablet contains 25 mg hydralazine hydrochloride Strips of 10 tablets and boxes of 10 strips of 10 s

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